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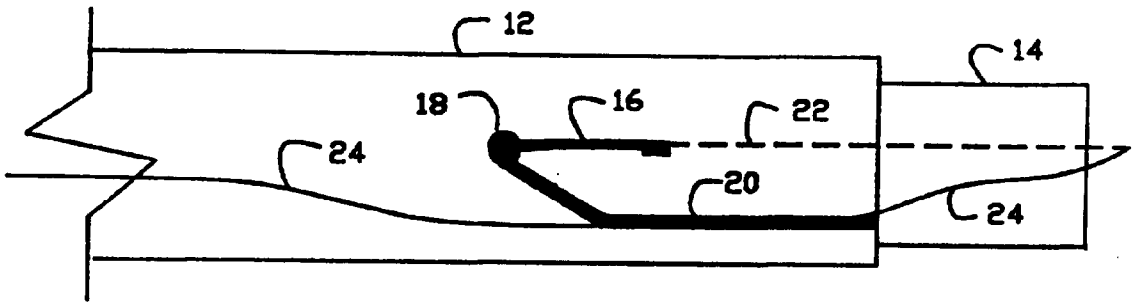

(57) Abstract

An anastomosis catheter is provided with internally mounted cam pieces holding a plurality of curved needles adjacent apertures in the side of the catheter is provided. The curved needles are attached to lengths of suture material which are installed to run along the outer surface of the central cam pieces to their distal end, where they reverse back along the inner core of the catheter. When the central cam pieces are withdrawn, and moved proximally, the cam surface forces the curved needles out the associated apertures. As the catheter is deployed in a hollow organ, such as a human urethra, the curved needles, as they are deployed, grasp the end of the urethra, which then can be held in position for suturing to the bladder. The other end of the suture materials could have straight needles attached to them to facilitate attaching the urethra to the bladder. A passive fixation device is also provided, defined by a generally elongated body with proximal and distal ends, and a connecting member to connect the two, is used for the anastomosis of body lumens without sutures. The proximal and distal ends are non-deployed in a non-deployed position, and are deployed in a deployed position. While in the non-deployed positions, the passive fixation device is inserted into one or more body lumens. After insertion, both the proximal and distal ends are deployed and become expanded. One end is first deployed, and then the other. The deployed proximal end becomes retained in a first lumen, and the deployed distal end becomes retained in a second lumen.

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ANASTOMOSIS CATHETER

FIELD OF THE INVENTION

This invention relates to an anastomosis catheter which is utilized for assisting in the joining together of two or more hollow body parts, and, more particularly, for example, for rejoining a transected urethra to the bladder after a radical prostatectomy.

BACKGROUND OF THE INVENTION

After certain operations are performed on a living body, and certain body parts been removed because of disease or other destruction of the organ, other body parts must be reconnected in order for the patient to survive and to maintain the remaining body functions. For example, in certain heart operations where bypass surgery is performed, sections of a person's coronary artery to the heart may either be completely replaced or actually bypassed during the heart bypass operation. While some of these arteries are large and are more easily manipulated by a surgeon, other arteries or hollow body organs are smaller and much more difficult to manipulate and hold in position while trying to join the ends thereof after a transectional operation.

In one instance, while a prostate gland is being removed in an operation called a prostatectomy, a section of the urethra is be removed when the prostate is removed, due to the occurrence of cancer in the prostate. After the operation to remove the prostate, the urethra must be reconnected to the bladder in order for the person to resume normal body functions, here, urination.

Heretofore, surgeons would grasp the end of a transected urethra, for example, and stretch it to the mating end of the urethra at the bladder perform delicate suturing operations with tiny, fine needles. Needless to say, some surgeons are very adept at this kind of anastomosis, but with radical prostatectomies becoming more common place, techniques for assisting in the rejoining of body parts, such as the urethra to the bladder, would be appreciated.

U.S. Patent 4,554,543, to Amarasinghe, issued November 19, 1985, reveals a plurality of flexible suture needles which are held in slots in a flared core by a sleeve which extends about the flexible suture needles and the core. The suture needles, and attached threads, are caused to penetrate the walls by a body duct, such as a blood vessel, by inserting the flared end of the core into the severed body duct and then forcing the needles to move longitudinally in the slots against the flared end of the core so that they bend outwardly and are driven through the wall of the duct. U.S. Patents to Avant, 4,848,367, issued July 18, 1989, 4,873,977, issued October 17, 1989, and 5,047,039, issued September 19, 1991, are all concerned with urethra and bladder anastomosis by varying techniques. Other U.S. patents to Tauber, 2,897,820; Demos, 4,784,139; Roth, 4,911,164; Gottesman, 5,053,043; McKeating, 5,078,721; Jain, 5,080,664; Roth, 5,207,672; and Rothe 5,209,725 are all related to prior attempts at anastomosis and tissue ligation.

SUMMARY OF THE INVENTION

The present invention includes a medical probe device comprising a catheter having a plurality of needle apertures in a side thereof, with an associated suture needle positioned within the catheter adjacent each needle aperture. The needle apertures are adjacent the distal end of the catheter, the needles being deployed outward of said needle apertures upon activation thereof. One embodiment provides for cam sections within the hollow catheter for urging the suture needles out of the needle apertures upon activation of the deploying apparatus. The cam sections are positioned for longitudinal movement thereof within the catheter, each cam section having at least one cam surface. Each cam surface contacts the associated suture needle upon activation, the cam surfaces operating to urge the needles outward of the needle apertures upon longitudinal movement of the cam sections.

Each suture needle can be curved such that the curve approximates that of the cam surface of the cam sections, with the needle riding in the space defined by the cam surface prior to activation of said deployment apparatus, with the needle

riding up on said cam surface and outward of said needle aperture upon the longitudinal movement of the cam sections. Each suture needle has a distal end and a proximal end, with the distal end having a sharp tip which is moved outward of the associated needle aperture, with its proximal end being attached to suture material or thread. The medical probe device further includes a plurality of slots in the side of the catheter running from each needle aperture to the proximal end of the catheter, the slots allowing the removal of the suture material from the catheter subsequent to deployment of each suture needle. Each suture needle is positioned within the catheter with the proximal end of the suture needle facing toward the distal end of the catheter. The suture material is attached to the needle being positioned longitudinally forward within the catheter toward the distal end thereof and around said cam sections and back through the center section of said catheter toward the proximal end of the catheter, wherein a loop of suture material remains beyond the distal end of the catheter subsequent to the deployment of each suture needle.

The medical probe device may further include a second suture needle attached to the other end of the suture material, wherein the suture material and the second needle is removable from the catheter via the slots in the side of the catheter. Depending on the internal construction of the catheter, the suture needles may be deployed upon distal movement of the cam sections within the catheter, or, alternatively, by the proximal movement of said cam sections.

Another embodiment for the medical probe device herein discloses a hollow catheter having a plurality of needle apertures in the side thereof for directing a plurality of suture needles outward through said needle apertures and through adjacent tissue, with a suture needle positioned in all or most of said apertures, and including apparatus for deploying the suture needles outward through the apertures. The deploying apparatus includes a wedge segment cylinder within the catheter which comprises a plurality of wedge segments for urging the suture needles out of the needle apertures upon activation of said deployment apparatus. Each of the wedge segments comprises cam segment and cam section

combinations which are generally of complementary cam shapes such that in one position each cam segment and cam section are substantially in a mating configuration. The cam segments are positioned for longitudinal movement thereof in the catheter, each of said cam segments having at least one cam surface, wherein the cam surfaces of the cam segments contact the suture needles upon activation, the cam surfaces operating to urge the suture needles outward of said needle apertures upon longitudinal movement of the cam segments.

In this embodiment, the suture needles are curved such that the curve approximates that of the cam surface of the cam segments, the needles riding in the space defined by the space between the cam segments and the cam sections prior to activation of the deployment apparatus, the needles riding up on said cam surface and outward of said needle apertures upon the longitudinal movement of the cam segments. Each of the suture needles has a distal end and a proximal end, the distal end having a sharp tip to be moved outward of each needle aperture, with the proximal end being attached to suture material. The medical probe device further includes a plurality of slots in the side of the catheter running from the needle apertures to the proximal end of the catheter, the slots allowing the removal of the suture material from the catheter subsequent to deployment of the suture needles.

The wedge segments can be selectively activated to individually deploy the suture needles, the suture needles being positioned within the catheter with the proximal ends of the suture needles facing toward the distal end of the catheter. The suture material attached to each of the suture needles is positioned longitudinally forward within the catheter toward the distal end thereof and around the wedge segments and back through the center section of the catheter toward the proximal end thereof, wherein a loop of the suture material remains beyond the distal end of the catheter subsequent to the deployment of the suture needles.

This embodiment also includes a plurality of second suture needles attached to the other end of each of the suture material, wherein the suture material and the second needles are removable from the catheter via said slots. Additionally, the

cam sections are fixedly attached within said catheter. Depending on the internal configuration of the catheter, the suture needles are deployed upon distal movement of the cam segments within the catheter, or can be deployed upon proximal movement of the cam segments within the catheter.

A passive fixation device is also provided which is defined by a generally elongated body with a proximal end and a distal end. The ends are connected by a connecting member. Both ends are non-deployed in a non-deployed position, and are deployed in a deployed position. While in the non-deployed positions, the passive fixation device is inserted into one or more body lumens. After insertion, both the proximal and distal ends are deployed and become expanded. One end is first deployed, and then the other. The deployed proximal end becomes retained in a first lumen, and the deployed distal end becomes retained in a second lumen.

In one embodiment, the first lumen is the bladder, and the second lumen is the urethra. The passive fixation device is positioned around a Foley type catheter that includes two inflatable balloons. The catheter, with the passive fixation device, is inserted into the urethra. The first balloon is inflated, causing the proximal end of the passive fixation device to become expanded to its deployed position and become retained in the urethra. At this time, the distal end of the catheter is either in the bladder, or if not then it is moved towards the bladder. Because the expanded deployed proximal end is now retained in the urethra, the urethra is also moved towards the bladder. The catheter passes through the urogenital diaphragm without causing any nicks or disruptions to its structure. After the proximal end of the passive fixation device has been introduced into the bladder in its non-deployed position, it becomes deployed, expanded and retained in the bladder. The urethra and bladder are now positioned in a contact or almost contact relationship so that the two can become anastomized. After each end of the passive fixation device is deployed, the associated balloon of the catheter is deflated. Once the proximal end of the passive fixation device is positioned and retained in the bladder, the catheter is then removed. Because the connecting member is of a much smaller size than either of the proximal or distal ends,

typically only a single strand of wire or small sheet or material, its interaction with the urogenital diaphragm is very limited. The risk of incontinence is minimized.

The passive fixation device can have coiled proximal and distal ends that are connected with a single strand of wire. Alternatively, it can be made of one or more sheets of material that can be expanded to the deployed positions. Preferably, the sheets include a plurality of perforations so that after anastomosis is complete the sheets can be gently unraveled along the perforations for easy removal through the urethra. When the coil is used, it becomes uncoiled after anastomosis and is also easily removed through the urethra with a resectoscope. Additionally, the proximal and distal ends of the passive fixation device can have different geometric configurations, depending on the application. Each may be conical, cylindrical as well as other geometries that are suitable for positioning and retaining the respective end in a desired body lumen.

The passive fixation device may consist of a tightly wound coil that becomes self-deployed as it is advanced out of a delivery catheter. Additionally, the passive fixation device can be made of a shaped memory metal. At either elevated or lower temperatures the coil is deployed, or it collapses, allowing it to be removed through itself.

A variety of different materials can be used for the passive fixation device. The coil can constitute different gauges of wire, depending on the body lumens to be anastomized. Both non-metals and metals can be used. Memory metals are suitable, as well as materials that are absorbable and dissolvable. Some dissolvable materials gradually dissolve as anastomosis proceeds, and can be passed through the urine when the application is the anastomosis of the bladder to the urethra. Other dissolvable materials can be activated with an initiating media such as ultra-sound.

Advantageously, the passive fixation device provides for the anastomosis of body lumens without the use of sutures, staples or clamps. It is particularly useful for the anastomosis of the urethra and bladder following prostatectomy because the urogenital diaphragm is not disrupted and the change of nicking it are

greatly reduced. The present invention is suitable with other surgical and microsurgical applications, particularly when it is desirable to avoid suturing.

DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the invention, reference may be had to the following detailed description of the invention in conjunction with the drawings wherein:

Fig. 1 is a top view of a first version of the distal end of a catheter in accordance with the principles of the present invention.

Fig. 2 is a side, sectional-view of the distal end of a catheter showing the suture needles prior to deployment.

Fig. 3 is a side, sectional-view of the distal end of a catheter in accordance with the principles of the present invention showing the suture needles after deployment.

Fig. 4 is a perspective view of the distal end of a catheter showing a second version of the present invention prior to needle deployment.

Fig. 5 is a perspective view of the embodiment of Fig. 4 after needle deployment.

Fig. 6 is the side view of a cam which is one part of a section of the embodiment Fig. 5.

Fig. 7a is a side view of a wedge section utilized in Fig. 5; while Fig. 7b is a view from the distal end thereof.

Fig. 8a is a bottom view of the wedge shown in Fig. 7; while Fig. 8b is a view from the distal end thereof.

Fig. 9 is a side-sectional view of the cam in Fig. 6 and the wedge in Fig. 7 prior to deployment of the suture needle.

Fig. 10 is a side-sectional view of the embodiment shown in Fig. 9 subsequent to the deployment of the suture needle and displacement of the suture material.

Fig. 11a is an enlarged view of the wedge section cylinder of the embodiment of Fig. 4; while Fig. 11b is a distal end view thereof.

Fig. 12a is an enlarged cross-sectional side view of the embodiment shown in Fig. 4 showing the wedge section cylinder within the confines of the catheter illustrating the placement of the suture needles and suture material; while Fig. 12b is a distal end view thereof prior to suture needle deployment; and Fig. 12c is a distal end view thereof with the suture needles deployed.

Fig. 13 is a side view of a third embodiment of the present invention showing the annular balloon, deployed needles and grasping handle.

Fig. 14 is a view of section A-A of the handle seen in Fig. 13.

Fig. 15 is a three dimensional side view of the handle portion of the catheter of this embodiment showing the deployment sliders for each of the suture needles;.

Fig. 16 is a cross-sectional side view of the embodiment shown in Fig. 15.

Fig. 17 is a proximal end view of the embodiment shown in Fig. 15.

Fig. 18 is a perspective view of one embodiment of the passive fixation device with coiled proximal and distal ends that are connected with a single strand of wire. The ends are in non-deployed positions.

Fig. 19 is a perspective view of a second embodiment of the passive fixation device made of one or more sheets of an expandable solid material that includes a plurality of perforations formed in the solid. The ends are connected by a single piece of solid material that has a much narrow cross-sectional area than the diameter of either of the proximal or distal ends. Both ends are shown in non-deployed positions.

Fig. 20 illustrates a third embodiment of the passive fixation device, in the non-deployed position. The solid material includes a plurality of perforations as well as apertures, thus making it a semi-solid structure.

Fig. 21 shows a coiled passive fixation device in a deployed position. The proximal end is expanded to a generally cylindrical geometry, while the distal end is substantially conical.

Fig. 22 shows a coiled passive fixation device in a deployed position with both the proximal and distal ends expanded to generally conical geometries.

Fig. 23 illustrates a coiled passive fixation device in a deployed position with both the proximal and distal ends expanded to generally cylindrical configurations.

Fig. 24 illustrates the passive fixation device of Fig. 19 in a deployed position with the proximal end expanded to a cylindrical configuration, and the distal end expanded to a generally conical shape.

Fig. 25 illustrates the passive fixation device of Fig. 19 in a deployed position with both the proximal and distal ends expanded to generally conical configurations.

Fig. 26 is a cross-sectional view of a Foley type catheter, with expanded balloon, used in certain embodiments with the passive fixation device.

Fig. 27 illustrates the human urological anatomy, and the introduction of the Foley catheter into the urethra.

Fig. 28 is a cross-sectional view of a Foley type catheter with two expanded balloons. The first balloon has a generally spherical shape, while the second one is conical.

Fig. 29 illustrates the placement of the passive fixation device in an adjacent surrounding relationship to the Foley catheter of Fig. 28 in a non-deployed state.

Fig. 30 illustrates the placement of the passive fixation device around the Foley catheter of Fig. 28. Both balloons have been expanded to deploy the passive fixation device. The proximal end has been expanded with a spherical balloon, and the deployed proximal end has a cylindrical geometry. The distal end has been expanded with a conical shape balloon which imparts a conical geometry to the distal end of the passive fixation device.

Fig. 31 shows placement of the passive fixation device in the urethra and bladder after deployment, with the proximal end of the passive fixation device

being expanded to be retained in the urethra, and the distal end expanded so that is seated and retained in the bladder.

Fig. 32 illustrates one method of uncoiling and removing a coiled passive fixation device by pulling on either end of the coil.

Fig. 33 illustrates the uncoiling of the coil of Fig. 32.

Fig. 34 shows that the coil has become substantially uncoiled as it is removed from a body structure such as the urethra.

Fig. 35 illustrates a tightly wound coil positioned in a delivery catheter.

Fig. 36 illustrates a tightly would coil, positioned in a delivery catheter, with a cam advancing the coil out of the delivery catheter.

Fig. 37 illustrates the deployed coil after it has been removed from the delivery catheter.

DETAILED DESCRIPTION OF THE INVENTION

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

Fig. 1 of the present invention is a side view of the distal end of a catheter utilizing the principles of the present invention. The distal end of catheter 12 is shown which could comprise a cylindrical or other generally round tubular device made of surgical stainless steel or other appropriate material. Adjacent the end of the catheter 12 would be an aperture, or hole 18, together with a slot 20 running at an angle from aperture 18 and then longitudinally along the length of the catheter to the distal end thereof. Needle 16 is, in this figure, totally within the confines, or central core, of the hollow catheter 12. One end of suture needle 16 is connected to suture material 22, which is shown in dashed lines in Fig. 1, as the suture

material is not seen in this Fig. as it is within the confines of the catheter 12 and cam section 14. The other end of suture 24, as it exits the central core of the cam section 14 and catheter 12, is seen as having been removed from the catheter by means of aperture 18 and slot 20. The other end of suture material 24 could be a straight needle which could be pulled out, and in this Fig. has already been pulled out, to utilize it in suturing the bladder to the urethra, for example. Once the suture has been made, the surgeon can continue to suture as desired utilizing the curved suture needle 16, and then tie off the suture in the normal course of the operation.

Fig. 2 is a side-sectional view of catheter 12 prior to deployment of the needles 16 and 16a. Cam sections 14 and 14a are in position with the distal ends of the cam sections protruding out beyond the distal end of the catheter 12. The catheter could be deployed, or inserted, in a hollow body organ such as the male urethra with the cam sections 14 and 14a in this position shown in Fig. 2, or the cam sections could have been installed in the catheter 12 with the cam sections further located proximally of the distal end of catheter 12 so that the distal end of cam sections 14 and 14a could be adjacent to or behind, or within the central core of the catheter 12. That is, if the cam section 14 is moved to the right before deployment as shown in Fig. 2, then the curved needle 16 will move along the inside edge of catheter 12 until the end 26 of needle 16 reaches aperture 18 where it will, due to the slight bias in the curved needle 16, snap into aperture 18 as shown in Fig. 2. Similarly, if cam section 14a had been further to the left in Fig. 2, upon deployment of cam section 14a to the right in Fig. 2, the needle 16a will snap into the aperture 18a, as shown in Fig. 2. Cam sections 15 and 15a on cam sections 14 and 14a enclose the curved needles, having the approximate shape thereof, prior to positioning as shown in Fig. 2. Cam sections 14 and 14a can be separate articles, separately activatable, on one tubular structure fitting inside catheter 12.

Fig. 3 shows the apparatus of Fig. 2 with the cam sections 15a and 15b retracted within the inner core of catheter 12. When the cam sections 14 and 14a are withdrawn from the distal end toward the proximal of the catheter 12, the cam

sections 15 and 15a exert pressure on curved needle 16 and 16a during the cam movements to the left and further force the curved needle 16 and 16a out through apertures 18 and 18a, as seen in Fig. 3. When the cams 15a and 15b are retracted, or withdrawn, from within the core of catheter 12, loops 24 and 24a of suture material are left protruding beyond the distal end of the catheter 12. This loop of catheter material 24 and 24a allows the operating surgeon to grasp the suture needle with a forceps device to withdraw the other end of the suture material out from within the central core of the catheter 12 for use in suturing the other organ to the present organ, such as, for example, a bladder to a transected urethra.

Fig. 4 is a three dimensional, perspective view of a second embodiment of the present invention. The anastomosis catheter 50 of this embodiment includes a catheter tube 52 which, again, could be surgical stainless steel. Adjacent the distal end of the catheter 52 are placed a series of apertures 54, 56, 58, annularly around the circumference of the catheter 52. Three apertures are shown in Fig. 4; however, more apertures may be utilized with a possibility of eight or more being included. Wedge segment cylinder 60 extends out from the distal end of the catheter 52 a short distance. As only three apertures are shown, the description will include only wedge segments 62, 64, and 66, but an examination of Fig. 4 will reveal a total of eight wedge segments, which will be operational for five additional apertures not seen in Fig. 4. Wedge segment cylinder 60 comprises eight wedge segments comprising the cylinder constructed such that there is a central hole which runs axially along the wedge segment cylinder within the central core of catheter 52. Seen also in Fig. 4 are eight suture materials which would be combined with the appropriate needle arrangement, not seen, in conjunction with the respective apertures. Thus, in Fig. 4, wedge segment 62, suture 63, and aperture 54 are in operational relationship; while wedge segment 64, suture 65, and aperture 56 are in operational relationship; and wedge segment 66, suture 67, and aperture 58 being in operational relationship together.

In Fig. 5, the wedge segment cylinder 60 is shown to have been extended further out from catheter 52. In Fig. 5, all of the wedge segments have been

deployed; however, each of the wedge segments can be operated individually, sequentially, or all together. As the wedge segment cylinder 60 is advanced in the distal direction in catheter 52, the suture material which is held taut over the ends of the wedge segments, pulls the curved needles which are attached to the end of each suture material. Thus, as each needle reaches its associated aperture, it is forced out of the aperture in the manner hereinafter described. Thus, as wedge 62 is advanced distally, suture material 63 is pulled along with it and when needle 69 reaches aperture 54, needle 69 is forced out of aperture 54 into its deployed position. Similarly, wedge segments 64 and 66 operate on suture material 65 and 67 to deploy needles 71 and 73 out of apertures 56 and 58, as seen in Fig. 5. The suture material, as described herein, could be typical suture thread material such as catgut, silk, cotton, nylon or other material but if the sutures are meant to be left in place within a living body, the suture material should be of the type that is absorbed by the body after the joining of the transected organs.

Figs. 6 through 10 are side section views of the wedge segments and cam devices for the embodiments shown in Figs. 4 and 5. Fig. 6, for example, depicts a cam section which is an elongated structure which tapers back from a leading thin edge thereof to a place adjacent the distal end thereof where the thin taper expands to a wide dimension to form a shoulder or a cam surface 76 seen in Fig. 6. That is, cam 70 has an elongated section culminating in distal front end 72 which tapers back along the surface 74 to reach a shoulder 76 which then becomes a wider section 78.

Fig. 7a is a side sectional view of the wedge segment 70 together with complementary designed cam follower 80. That is, cam section 70 is wedge shaped and includes the front section 72 which tapers back at area 74 to a rounder section 76 to the remaining part of the shaft at 78. Cam section 80 includes the shape complementary to the cam 70. That is, cam section 80 includes a section 74a which is complementary to the shape 74 of the cam 70. Moving away from the distal end thereof, shape 74 reaches a point where a rounder section 82 mates exactly with shape 76 of cam 70. The front view of the wedge segment is shown

in Fig. 70b. Wedge segment 84 includes the cam segment 70 and the cam section 80. Together they form wedge segment 84 which could be one of the wedge segments seen in Figs. 4 and 5.

Fig. 8a is a bottom view of the same wedge segment seen in Fig. 7a and Fig. 7b. Seen on the bottom of Fig. 8a is the aperture 88 from which the curved needle will emanate upon deployment. Slot 90 is provided to allow the removal of the needle and the suture material without having to pull it through the entire mechanism. Fig. 8b is the same as Fig. 7b but is oriented to show the relative position and configuration of the cam segment 70 and the cam section 80. Fig. 9 is a side-sectional view of the apparatus shown in Figs. 6 to 8, but now in working relationship together with a needle and suture material. Cam segment 70 is shown in its undeployed state away from its mating position with cam section 80. Positioned in the space between the cam surface 76 of cam 70 and cam surface 82 of cam section 80 is the curved needle arrangement 94. Attached to the inner end of curved needle 94 is a suture material 92 which is seen to run forward toward the distal end of the catheter and then around the front thereof and back along the cam segment 70 which is the hole 96 seen in Fig. 4.

Fig. 10 is a side view of the same arrangement seen in Fig. 9 with, however, the cam section 70 moved distally along the core of the catheter until the cam surface 76 comes in contact with curved needle 94 which, upon movement of the cam 70 to the distal end, or right side of Fig. 10, forces the curved needle 94 out aperture 88 with the curved needle operating as a cam follower in this instance. At the same time, the cam surface 76 is forcing the curved needle 94 out of aperture 88, the distal end of cam segment 70 is forcing additional suture material out the front of the catheter which, as set forth above, allows an operating surgeon to grasp the suture material with a forceps or other grasping device to pull the suture material out from the central core of the catheter. As set forth above, the other end of the suture material from the curved needle 94 could have a straight needle attached to it to facilitate the suturing of the bladder to the transected end of the urethra, for example.

Fig. 11a is a side view of the wedge section cylinder 60 seen in conjunction with Figs. 4 and 5. The side view 11a of the wedge section cylinder 60 comprises wedge segments 62 and 64 as seen in Figs. 4 and 5. Shown in representative form are slots 90 and 90a for wedge section segments 62 and 64. Fig. 11b is a view from the distal end of wedge section cylinder 60 including eight such wedge segments 84 which are the type shown and described in conjunction with Figs. 6 to 10.

Fig. 12a is a cross-sectional view similar to that of Fig. 11a, but Fig. 12a includes a side view of the catheter 52 so that the relative placement of the wedge section cylinder 60 can be seen in relation to the catheter 52. Positioned in grooves 90 and 90a are the suture material 92 and 92a which are seen to run in the grooves 90 and 90a which are similar to the groove seen in conjunction with Fig. 8a. The suture material 92 runs along the bottom edge of each wedge section and across the front or distal end of the wedge section cylinder 60 and then back along the center opening 96. In Figs. 12a and 12b are eight such wedge segments which could be in less number or greater number, but, for convenience, eight are shown in Fig. 12b. Fig. 12c is a Fig. similar to Fig. 12b; however, the curved needles have been deployed out of each representative or associated aperture hole in order to deploy the curved needles into the urethra as is desired.

In operation, an operating surgeon would manipulate slide sections as desired to move each cam segment into position. As each cam segment is in position, each associated curved needle is deployed out the associated aperture holes into the inner wall and out the outer wall of the body tube, here, for example, a urethra. In this manner, the urethra can be positioned adjacent the complementary tube emanating from the bladder, while the catheter invention as disclosed allows for accurate placement and removal of the center suture material lengths which are or may be attached to straight needles mounted on the inner core of the catheter arrangement. That is, at the desire of the operating surgeon, each curved needle would be deployed to grasp the inner surface of the urethra. As described above, this allows a section of the suture material to be grasped by a

forceps or other device by the operating surgeon who can then remove the straight needle from the center core of the catheter. These straight needle segments can be used to begin the suturing action for each of the curved needles at the other ends of the suture material to sew the transected ends of the male urethra and battery together to allow the mating of these transected ends to be joined in a permanent manner.

Fig. 13 is a three dimensional isometric view of still another embodiment of the present invention. Catheter 100 includes an elongated cylindrical body 102 which has several axial lumens built therein. Catheter 100 further includes a central lumen which is longitudinally extended. It can be made of plastic or surgical steel. Axial lumen 104 is parallel to the axis of the catheter 100, but near the distal end of the catheter it makes a sharp turn to the outer surface of the catheter terminating at aperture 108. In lumen 104, and exiting at aperture 108 is suture material or thread 106 which has a sharpened end to allow for penetration of body tissue or it could comprise a suture with a sharpened needle to effect the same result. The suture could be made of any appropriate suture material, such as vicryl or surgical gut. The suture material with the sharpened end 106 exits the catheter at aperture 108 at approximately a 60 degree angle due to the curve of the lumen 104 as it approaches aperture 108. The angle at which the suture material exits the catheter 100 can be adjusted by the severity of the angle at which the lumen approaches aperture 108. A similar lumen would be associated with aperture 14 as well as a similar suture material for aperture 116. However, to simplify Fig. 13, the sutures are not seen to emanate from apertures 114 to 116. Annularly around the distal end of the catheter is a marker band 120. This marker band could either be compressed into the surface of the catheter or could be a different material such as a painted surface to mark this position. The marker band 120 is approximately 3 mm back from the distal end 122 of the catheter 100. The marker band could be about 1 millimeter forward of the apertures 108, 114, and 116, which themselves are approximately 1 1/2 cm in front of an annular elastic balloon 130. This balloon is mounted on the outside surface of the catheter 100

and inflated by a lumen more clearly seen below in conjunction with Fig. 18. At the distal end 122 of catheter 100 is the opening 124 of a lumen 110 which includes a traction handle 126 that is moveable in the longitudinal axial direction into and out of catheter 100. This traction handle would be approximately eight inches long as it extends out of the distal end of catheter 100.

Fig. 14 is a cross-sectional view of the catheter as seen at section A - A of Fig. 13. Six lumens are shown in the cross section which carry the sutures seen and described in Fig. 13. That is, lumen 104 in Fig. 14 is the same as lumen 104 in Fig. 13 and carries suture 106 inside lumen 104. Similarly, lumen 131 carries suture 132, and in a similar manner the other four lumens would similarly carry associated sutures. Also in Fig. 14 is central lumen 110, which is also seen in Fig. 13, and carries within it the traction handle 126. Traction handle 126 is preferably made of plastic and runs through the center of catheter 100. It is capable of longitudinal movement. It is a long narrow rod with a round end 127. It enables the present invention to stretch the urethra to bring it into close proximity of the bladder. This is done by extending traction handle 126 toward the top of the page. In this process, round 127 stretches the urethra. Once the urethra is positioned in close proximity of the bladder, catheter 100 can be used to sew the two parts together. At the bottom of Fig. 14 is lumen 134 which would carry the balloon inflation and deflation material, which could be air, but more likely a modified saline solution. Balloon 130 could be made of any elastic materials such as vicryl, silicone or latex. It is attached to the outer surface of catheter 100 using different techniques. For example, if balloon 130 is made of silicon, adhesive material could be used to attach it to catheter 100. On the other hand, if latex is used to make balloon 130, known mechanical bonding methods could be used to attach it to catheter 100.

Fig. 15 is a three dimensional side view of the handle 150 of the catheter of the present invention. Section 150 of the catheter 100 includes three deployment sliders 152, 154, and 156 which are connected inside the handle arrangement 150 to a suture material as seen in Fig. 13. However, inasmuch as the suture material

is more easily pulled than pushed, the traction handle 126 would be more likely utilized to pull each of the deployment sliders which would deploy each of the suture ends 106 into the urethra, in this example. Deployment sliders 152, 154, and 156 would be utilized to withdraw toward the proximal end 158 of handle 150 each of the suture material filaments upon completion of the attachment of the urethra to the bladder.

Fig. 16 is a side view of handle 150 seen and described in conjunction with Fig. 15. Balloon inflation lumen 134 is formed in the handle which is connected to an external source of fluid for inflation thereof. The proximal end 136 of the traction handle 126 is shown in its lumen 138; while lumen 160 is shown to include the proximal end 162 of a suture material 106. Handle 156 is seen to be attached to suture 106 in a guide path not seen in Fig. 16 but clearly shown as slide path 157 in Fig. 15.

Fig. 17 is an end view of the handle shown and described in conjunction with Fig. 15. Lumen 110 is shown which would house the traction handle 136; while lumen 104 and the other five lumens are shown as suture delivery lumens in Fig. 17. Also included is the balloon inflation lumen 134.

In operation, the catheter 100 would be inserted into the patient's urethra and passed in the urethra until the transected end of the urethra is at the marker band 120 as seen in Fig. 13. The distal end of catheter 100 would be protruding beyond the end of the transected urethra. Upon selective actuation of deployment sliders 152 and any of the other deployment sliders, the sharpened ends of sutures 106 would be deployed into the end of the urethra by the operating surgeon. By utilizing needle forceps, each of the sutures can be pulled out of the catheter for use in suturing the urethra to the complementary end thereof on the bladder of the patient. Alternatively, the traction handle may be grasped by the surgeon which will deploy all of the sharp sutures into the urethra at one time. After the urethra has been re-attached to the bladder, the deployment handles can be moved rearwardly to the proximal end of the handle 150 which will withdraw the sutures material subsequent to cutting thereof by the operating surgeon. Then the entire

catheter can be slowly removed from the urethra after deflation of the balloon 130. This leaves the urethra attached to the bladder, having been accurately positioned thereto and sutured by the operating surgeon.

Shown in these latter Figs. are, in cross-section, six lumens carrying sutures while on the side views there are shown three apertures containing sutures. However, the invention is not limited to six but could include more apertures with sharpened sutures in accordance with the principles of the present invention.

As mentioned above, the device of the present invention can be used where there is a need to reattach two tubes with the body. In addition to the situation where the urethra must be connected to the bladder, the present invention can be used to connect the bottom end of the colon to the anus after the rectum is removed to cure colon cancer.

A passive fixation device, suitable for the anastomosis of vessels, ducts, organs, or other body structures, collectively body lumens, is illustrated in Figs. 18 through 20. For purposes of the present invention, a passive fixation device is one where ends or areas of body lumens are brought together in an adjacent, or nearly adjacent relationship, held there a sufficient length of time in order to permit anastomosis of the lumens to occur without the use, or alternatively the minimal use of sutures, staples, clamps, or other invasive retaining structures. Preferably, anastomosis proceeds without the use of such invasive retaining materials.

A generally elongated body 210 with a proximal end 212, a distal end 214 and a connecting section 216. Ends 212 and 214 can be in deployed and non-deployed positions. In Figs. 18 through 20, ends 212 and 214 are illustrated as being in non-deployed positions. In the non-deployed positions, passive fixation device 210 is inserted into a desired body lumen, including but not limited to the urethra and bladder. The non-deployed positions provide for the easy introduction of passive fixation device 210 into the body lumen, without damaging the lumen. If passive fixation device 210 is introduced into the body lumen in a deployed position, then it is far more difficult to insert device 210 into the lumen without cutting, shearing, taring or imparting some other sort of damage to the lumen.

In Fig. 18, passive fixation device 210 is made of a coiled proximal end 212, coiled distal end 214 and a single strand of connecting medium, including but not limited to a wire-like structure. Coiled ends 212 and 214 are shown as being generally cylindrical in the non-deployed positions, but other geometric configurations are possible. In Fig. 19, passive fixation device 210 is made of a generally solid material, which may consist of one or more sheets. Preferably, the solid material includes a plurality of perforations in order to facilitate the removal of passive fixation device 210 from the confined area once anastomosis is complete, or nearly complete, as more fully explained hereafter in this specification. Ends 212 and 214 are connected by a generally narrow, connecting section 216, made of preferably the same material as ends 212 and 214. Fig. 20 shows that instead of a completely solid structure, passive fixation device 210 can be made of a generally solid material. In Fig. 20, one embodiment is shown where the solid material is semi-solid and includes a plurality of apertures and perforations. The solid material has sufficient structural integrity so that it can be expanded to the deployed position and remain deployed so that ends 212 and 214 become retained in their respective lumens. Thus instead of the coiled structure of Fig. 18, it is possible to employ a solid structure, or one that is nearly solid, so long as in the deployed position ends 212 and 214 remain sufficiently expanded and deployed to be retained in the desired lumen.

Figs. 21 through 25 show ends 212 and 214 in different deployed geometric configurations. In Fig. 21, proximal end 212 is deployed to a generally cylindrical shape while distal end 214 is expanded to a conical configuration. Proximal and distal ends 212 and 214 are expanded to conical geometries in Fig. 22, while in Fig. 23, proximal and distal ends 212 and 214 are expanded to generally cylindrical shapes. In Figs. 24 and 25, passive fixation device 210 is made of a substantially solid material and proximal and distal ends 212 and 214 are expanded to conical and cylindrical geometries respectively.

While proximal and distal ends 212 and 214 are inserted into desired body lumens, they are usually in the non-deployed positions in order to permit easy

insertion with minimum disruption to the body lumen. In deployed positions, each end 212 and 214 is expanded so that least a portion of the end has a diameter that is greater than at least a portion of the body lumen where it is deployed. In this manner, proximal and distal ends 212 and 214 are retained within the lumens and become temporary fixed therein until anastomosis is complete, or complete enough so that passive fixation device 210 can be removed from the lumen. Sufficient expansion in the deployed position is produced in order to achieve the desired retaining effect. For example, if two vessels are to be joined, proximal and distal ends 212 and 214 are initially positioned in the two vessels in non-deployed positions. They are subsequently deployed, causing each end 212 and 214 to have at least a portion with a diameter that is greater than at least a portion of the lumen's diameter in which ends 212 or 214 become retained. If the lumen is a body organ, either proximal or distal end 212 or 214 is inserted into the organ in the non-deployed position, and then expanded to the deployed position with at least a portion of its diameter greater than at least the diameter of one section of the organ, permitting the deployed end to become "seated" in the organ.

Referring once again to Fig. 18, and without limiting the scope of the present invention, in one embodiment passive fixation device 210 has a proximal end 212 with length of about 1.5 cm, connecting member 216 length of about 2.5 cm and distal end 214 length of about 2.5 cm. The coil is made of 32 French wire.

A variety of materials can be used for passive fixation member 210, including but not limited to materials suitable for coiling such as different gauges of wire. The wire can be made of biocompatable materials including various metals such as copper, nitinol and memory wire. Additionally, a wire like structure can become coiled with the application of a first current, and uncoiled when a second is applied. Different solid materials, or semi-solid materials, that can be used include but are not limited to plastics, polyester, polyolefin, nylon, polyurethane, and the like. Other suitable materials are absorbable by the body once anastomosis is sufficiently completed that passive fixation device 210 is no longer needed. Additionally, dissolvable materials, that can pass through the body,

for example with different body fluids such as blood, urine, and the like, can be used. Some of the materials can be dissolved upon the application of an activating mechanism including but not limited to ultra-sound. A tab can incorporated into either end of proximal or distal ends 212 and 214, in order to facilitate remove of passive fixation device 210 from the body structure. The tab can be in the form of a turned up bead that can be lifted up away from its point of contact with a body lumen, and then it is pulled out through itself. This is particularly useful when distal end 214 is unseated and the coil pulls through itself with minimal disruption of body lumens. The tab can also serve the purpose, in certain applications, of being seated within the body lumen so as to engage and retain proximal or distal ends 212 and 214 therein.

Passive fixation device 210 can be inserted into a body lumen with the use of a catheter, such as a Foley catheter 218 of Fig. 26. Foley catheter 218 is particularly useful for urology applications, but it will be appreciated that the present invention is not limited to urology. For purposes of the following discussion, the use of Foley catheter 218 will be for anastomosis of a urethra with a bladder following a prostatectomy.

Catheter 218 has en elongated tube 220 that has a proximal end 222 that remains outside of a patient's body, and a distal end 224 that is eventually placed in the patient's bladder. Catheter 218 is inserted through the urethra as shown in Fig. 29. Elongated tube 220 includes a main lumen 226 extending from an inlet opening 228, located at distal end 224 of catheter 218, to proximal end 222.

An inflation lumen 230 extends through elongated tube 220 connecting a source of fluid located at the exterior to the patient's urethra (not shown) at proximal end 222_to a balloon 232. Inflation lumen 230 terminates in an inflation outlet 234 formed in elongated tube 220. Introduction of fluid causes balloon 232 to inflate, and it deflates when the fluid is removed.

As shown in Fig. 28, catheter 218 includes two balloons, 234 and 236 which are inflated by one or more inflation lumens 230 and 238. This embodiment is particularly suitable for use of passive fixation device 210 following

prostatectomy for the anastomosis of the urethra with the bladder in a sutureless procedure. Passive fixation device 210 is positioned around the exterior of elongated tube 220 in Fig. 29. In Fig. 30, passive fixation device 210 is positioned so that balloons 232 and 236 are inflated, causing proximal end 212 and distal end 214 to be expanded to their deployed positions.

Catheter 218 can also include one or more distensible members that are mechanically extended and retracted in order to deploy proximal and distal ends 212 and 214 of passive fixation device. An actuator causes the distensible members to become mechanical distended. After proximal and distal ends are deployed, the distended ends are retracted. The distensible members can be used in place of balloons 232 and 236.

The geometry of balloons 232 and 236 can be such that when inflated they impart various geometrical configurations that are then used to expand proximal and distal ends 212 and 214. As shown in Fig. 30, balloon 232 is inflated to a conical shape, causing distal end 214 to become expanded to the conical coil shown in Fig. 21. Balloon 236 expands spherically, causing proximal end 212 to become cylindrically expanded, as also shown in Fig. 21. Other geometries of balloons 232 and 236 are possible, depending on the desired deployed shape of distal end 214 and proximal end 212. It will be appreciated that the deployed proximal and distal ends 212 and 214 of passive fixation device 210 can be initially formed such that when an expanding force, such as imparted by either balloon 232 or 236, is applied to ends 212 and 214 they will form the desired deployed geometries. For example, a coil may be wound with various degrees of winding intensity such that with an even application of force, such as with a spherical balloon, it will become deployed in a conical geometry.

With reference again to Fig. 29, catheter 218 and passive fixation device 210 are inserted into the urethra, as shown in Fig. 27, following the removal of the prostate. While inserted into the urethra, proximal and distal ends 212 and 214 of passive fixation device are in non-deployed positions. As proximal end 212 is near the distal end of the urethra it is deployed and expands to a cylindrical, conical or

other geometric configuration, such that proximal end 212 becomes retained in the urethra. Balloon 236 can then be deflated. At this time, distal end 214 of passive fixation device 210 may already be within the bladder. If not, then catheter 218 is advanced further, without disrupting the urogenital diaphragm, with distal end 224 of catheter 218, and distal end 214 of passive fixation device, entering the bladder. Balloon 232 is then deployed, causing distal end 214 to become deployed in a conical or other suitable geometry so that distal end 214 becomes retained within the bladder. As catheter 218 is advanced into the bladder, the distal end of the urethra is moved in a position adjacent, or nearly adjacent to the bladder. As shown in Fig. 30, upon deployment of distal end 214 of passive fixation device 210, the bladder and distal end of the urethra are urged towards each other in a relationship that permits anastomosis between the two. Now that passive fixation device 210 is retained in both the urethra and bladder, catheter 218 can be removed, or it can remain for a desired time to permit drainage of urine through catheter 218.

After a time period, such as for example, but not limited to thirty (30) days, anastomosis is essentially complete. Passive fixation device 210 can then be removed. Alternatively, it may have already become absorbed by the body or dissolved and passed through the urine.

Passive fixation device2 10 is readily removed by using a resectoscope, or other suitable instrumentation, to physically grab either proximal or distal end 212 and 214 and pull. The unwinding of the coil is shown in Fig. 33. It will be appreciated that distal end 214 of passive fixation device 210 can be uncoiled when a resectoscope, cystoscope, or the like grabs distal end 214 at the turned up bead portion, unseats the bead from the interior of the body lumen, distal end is then pulled out through passive fixation device 210 and readily is uncoiled, removed through itself with minimal disruption to body lumens. Fig. 34 illustrates that the coil becomes generally elongated as it is unwound and is readily removed through the urethra. If passive fixation device 210 is made of a solid material with perforations, then the resectoscope grabs the solid material and unwinds it along the perforations as the resectoscope is pulled away from the bladder.

It will be appreciated that the present invention is applicable to a variety of body lumens other than the urethra and bladder.

In another embodiment of the invention, passive fixation device 210 has proximal and distal ends 212 and 214 respectively, that are tight coils in the non-deployed (deactivated) states, and each end becomes self expanded in the deployed (activated) state. In this embodiment, passive fixation device 210 is a tight coil when it is positioned and delivered through the use of a delivery catheter 240 (Fig. 35). Passive fixation device 210 can be placed in the desired body lumen, and its position can be determined by including a platinum, gold, or the like marker at distal end 214. Through the use of ultra sound, or the like, the position of distal end 214 is then determined. Passive fixation device 210 can be a coil, cone or the like, however, for ease of discussion will be referred to as a coil, is wound tightly and is in non-deployed (deactivated) state and must be contained or it will become deployed without the use of balloons or some mechanism to expand it. The coil fits easily within the lumen of delivery catheter 240. Delivery cathode 240 is then pulled away from the desired body lumen where the coil is to be positioned, and with the removal of delivery cathode 240 the coil begins to unwind to its deployed (activated) state. The unwinding of the coil, with the removal of delivery catheter 240 is illustrated in Fig. 36. Optionally, delivery catheter 240 can include a mandrel 242 which pushes the coil out of delivery catheter 240. Mandrel 242 is of sufficient size to occlude the lumen, like a ram rod, yet remain longitudinally manipulable over the tortuous course of a body lumen like the urethra or other delivery path. Delivery catheter 240 can be still, to aid in the positioning of the coil. As is shown in Fig. 37, the coil is fully deployed once delivery catheter 240 is removed. It will be appreciated that a solid sheet of material, in place of the wound coil, can also be employed with this embodiment.

As previously mentioned, the coil can be made of a shaped memory metal, such as nickel titanium, available from Raychem, Menlo Park, California. In one embodiment, the coil is heated and expanded. Additionally, the coil can be preloaded so at a temperature, such as 37 degrees C, it is expanded. At 20 degrees

C, it remains as a tight coil and non-deployed. In this instance, the body lumen itself provides the heat to deploy the coil. It is initially at this lower temperature. When introduced into the desired body lumen, it becomes deployed with the heat from the body lumen. The coil can be cooled before insertion and activated with an electrical current. It is also possible to heat the coil to a temperature above the body lumen temperature, e.g., 45 degrees C, before insertion. After insertion, the body lumen brings the coil's temperature down to about 37 degrees C. In any of this embodiments, temperature, current, and the like are used to cause the tight coil to become activated, deployed, positioned, and seated in the respective body lumens. This enables the coil to take its deployed shape. In all of these embodiments, the reverse temperature parameter is applied to the coil when it is removed. This causes a collapse of the coil.

While the invention has been described with reference to specific preferred embodiments, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the true spirit and scope of the invention. In addition, many modifications may be made without departing from the essential teachings of the invention.

CLAIMS

WHAT IS CLAIMED IS:

1. A medical probe device comprising a hollow catheter having at least one needle aperture in a side thereof for directing a suture needle outward through at least said one needle aperture and through adjacent tissue, a suture needle positioned in at least one of said apertures, and deployment means for deploying said at least one suture needle outward through at least one of said apertures, said deployment means comprising cam section means within said hollow catheter for urging said suture needle out of said needle aperture upon activation of said deployment means.

2. The medical probe device of Claim 1 wherein said cam section means is positioned for longitudinal movement thereof in said catheter, said cam section means having at least one cam surface.

3. The medical probe device of Claim 2 wherein said cam surface of said cam section means contacts said suture needle upon activation, said cam surface operating to urge said needle outward of said needle aperture upon longitudinal movement of said cam section means.

4. The medical probe device of Claim 3 wherein said suture needle is curved such that said curve approximates that of said cam surface of said cam section means, said needle riding in the space defined by said cam surface prior to activation of said deployment means, and said needle riding up on said cam surface and outward of said needle aperture upon said longitudinal movement of said cam section means.

5. The medical probe device of Claim 4 wherein said suture needle has a distal end and a proximal end, said distal end having a sharp tip and moved outward of said needle aperture, and said proximal end being attached to suture material.

6. The medical probe device of Claim 5 further including a slot in said side of said catheter running from said needle aperture to the distal end of said catheter, said slot allowing the removal of said suture material from said catheter subsequent to deployment of said suture needle.

7. The medical probe device of Claim 6, wherein said suture needle is positioned within said catheter with the proximal end of said suture needle facing toward the distal end of said catheter, the suture material attached to said needle being positioned longitudinally forward within said catheter toward the distal end thereof and around said cam section means and back through the center section of said catheter toward the proximal end of said catheter, wherein a loop of said suture material remains beyond the distal end of said catheter subsequent to the deployment of said suture needle.

8. The medical probe device of Claim 7 further including a second suture needle attached to the other end of said suture material, wherein the suture material and the second needle is removable from said catheter via slot.

9. The medical probe device of Claim 8 wherein said suture needle is deployed upon distal movement of said cam section means within said catheter.

10. The medical probe device of Claim 9 wherein said suture needle is deployed upon proximal movement of said cam section means within said catheter.

11. A medical probe device comprising a hollow catheter having a plurality of needle apertures in the side thereof for directing a plurality of suture needles outward through said needle apertures and through adjacent tissue, a suture needle positioned in all or most of said apertures, and deployment means for deploying said suture needles outward through said apertures, said deployment means comprising a wedge segment cylinder means within said catheter, said wedge segment cylinder means comprising a plurality of wedge segment means within said hollow catheter for urging said suture needle out of said needle aperture upon activation of said deployment means.

12. The medical probe device of Claim 11 wherein said wedge segment cylinder means comprises a plurality of wedge segment means positioned in a cylinder shape and radially within said catheter, each of said wedge segment means comprising cam segment means and cam section means combinations.

13. The medical probe device of Claim 12 wherein said cam segment means and said cam section means are generally of complementary cam shapes such that in one position, said cam segment means and said cam section means are substantially in a mating configuration.

14. The medical probe device of Claim 13 wherein said cam segment means are positioned for longitudinal movement thereof in said catheter, each of said cam segment means having at least one cam surface.

15. The medical probe device of Claim 14 wherein said cam surfaces of said cam segment means contacts said suture needles upon activation, said cam surfaces operating to urge said needles outward of said needle apertures upon longitudinal movement of said cam segment means.

16. The medical probe device of Claim 15 wherein said suture needles are curved such that said curve approximates that of said cam surface of said cam segment means, said needles riding in the space defined by the space between said cam segment means and said cam section means prior to activation of said deployment means, and said needles riding up on said cam surface and outward of said needle apertures upon said longitudinal movement of said cam segment means.

17. The medical probe device of Claim 16 wherein each of said suture needles have a distal end and a proximal end, said distal end having a sharp tip and moved outward of said needle aperture, and said proximal end being attached to suture material.

18. The medical probe device of Claim 17 further including a plurality of slots in said side of said catheter running from said needle apertures to the distal end of said catheter, said slots allowing the removal of said suture material from said catheter subsequent to deployment of said suture needles.

19. The medical probe device of Claim 18 wherein said wedge segment means are selectively activated to individually deploy said suture needles.

20. The medical probe device of Claim 19, wherein said suture needles are positioned within said catheter with the proximal ends of said suture needles facing toward the distal end of said catheter, the suture material attached to each of said suture needles being positioned longitudinally forward within said catheter toward the distal end thereof and around said wedge segment means and back through the center section of said catheter toward the proximal end thereof, wherein a loop of said suture material

remains beyond the distal end of said catheter subsequent to the deployment of said suture needles.

21. The medical probe device of Claim 20 further including a plurality of second suture needles attached to the other end of each of said suture material, wherein the suture material and the second needles are removable from said catheter via said slots.

22. The medical probe device of Claim 21 wherein the cam section means are fixedly attached within said catheter.

23. The medical probe device of Claim 22 wherein said suture needles are deployed upon distal movement of said cam segment means within said catheter.

24. The medical probe device of Claim 22 wherein said suture needles are deployed upon proximal movement of said cam segment means within said catheter.

25. A medical probe device for assisting in joining together two or more body parts comprising:

a) a hollow catheter having a plurality of needle apertures in a side thereof for directing suture needles outward through said needle apertures and through adjacent tissue,

b) deployment apparatus for deploying each suture needle outward through said needle apertures, said deployment apparatus comprising individual cam sections within said hollow catheter for urging each suture needle out of said needle aperture upon deployment thereof, each of said cam sections having at least one cam surface and being positioned for longitudinal movement

thereof in said catheter, wherein said cam surface contacts said suture needle upon activation, said cam surface operating to urge said needle outward of said needle aperture upon longitudinal movement of said cam section,

c) a suture needle positioned in each of said apertures, each said suture needle being curved such that said curve approximates that of the curve of the cam surface of said cam sections, each said needle riding in the space defined by said cam surface prior to activation by said deployment apparatus, and said needle riding up on said cam surface and outward of said needle aperture upon said longitudinal movement of said cam sections, each said suture needle having a distal end and a proximal end, said distal end having a sharp tip and moved outward of said needle aperture, and said proximal end being attached to suture material, and

d) a plurality of slots in the side of said catheter running from each said needle aperture to the distal end of said catheter, said slots allowing the removal of said suture material from said catheter subsequent to deployment of said suture needle, wherein said suture needle is positioned within said catheter with the proximal end of said suture needle facing toward the distal end of said catheter, the suture material attached to said needle being positioned longitudinally forward within said catheter toward the distal end thereof and around said cam section means and back through the center section of said catheter toward the proximal end of said catheter, wherein a loop of said suture material remains beyond the distal end of said catheter subsequent to the deployment of said suture needle.

26. The medical probe device of Claim 25 further including a second suture needle attached to the other end of said suture material, wherein the suture

material and the second needle is removable from said catheter via said slot.

27. The medical probe device of Claim 26 wherein said suture needle is deployed upon distal movement of said cam section means within said catheter.

28. The medical probe device of Claim 27 wherein said suture needle is deployed upon proximal movement of said cam section means within said catheter.

29. A medical probe device for assisting in the joining together of two or more hollow body parts comprising:

a) a hollow catheter having a plurality of axial lumens running from the proximal end of said catheter to a position adjacent the distal end of said catheter, each of said lumens curving at the distal ends thereof to exit the catheter in an annular ring of apertures,

b) a sharpened suture in each of said lumens, said sharpened sutures comprising suture material with a distal end and a proximal end, and

c) a deployment slider for each of said sutures and attached thereto and positioned at the proximal end of said catheter for selectively deploying each of said sharpened sutures out of said axial lumens via said apertures into surrounding tissue.

30. The medical probe device of Claim 29 further including:
a marker band distally forward of said annular ring of apertures for accurately positioning of said catheter within the hollow body part.

31. The medical probe device of Claim 30 further including:

a) an annular elastic balloon positioned proximally rearwardly of said annular ring of apertures to stabilize said catheter within said hollow body part upon inflation of said balloon,

b) a balloon inflation lumen in said catheter parallel to said plurality of axial lumens coupled to said balloon to provide a path for inflation material to said balloon.

32. The medical probe device of Claim 31 further including:
a traction handle emanating from the distal end of said catheter to aid in inserting and positioning said catheter within said hollow body part.

33. The medical probe device of Claim 32 further including:
a gripping handle at the proximal end of said catheter of a larger overall diameter of said catheter for firm grasping by an operator, said gripping handle comprising said deployment sliders in an annular arrangement about the exterior of said handle, each of said deployment sliders being mounted in an axial guide path for longitudinal movement therein to deploy or withdraw said sharpened sutures.

34. The medical probe device of Claim 33 wherein said sharpened suture comprises a suture material having a sharp point thereon at the distal end thereof.

35. The medical probe device of Claim 33 wherein said sharpened suture comprises a needle with a sharp end and a proximal end, and suture material attached to the proximal end of said needle.

36. A passive fixation device comprising:

a generally elongated body with a proximal end, a distal end, a longitudinal axis and a connecting member connecting the distal and proximal ends, with a non-deployed distal end and a non-deployed proximal end in a non-deployed position, each end being expandable to a deployed distal end and a deployed proximal end in a deployed position, each of the ends being in the non-deployed positions while being inserted into a first and a non-connected second body lumens, and each end of the proximal and distal ends having configurations which self-radially expand in the deployed position in the first and non-connected second body lumens urging and positioning the first and non-connected second body lumens together along the longitudinal axis and become connected; and

an elongated body introducer for introducing the proximal and distal ends into the first and non-connected second body lumens in their non-deployed positions, and wherein upon removal of the elongated body introducer from the body lumens the proximal and distal ends self-expand to their deployed positions.

37. A passive fixation device comprising:

an elongated body including a longitudinal axis, a coiled proximal end and a coiled distal end connected by a connecting member, with a non-deployed coiled distal end and a non-deployed proximal end in a non-deployed position, and each end being expandable to a deployed coiled distal end and a deployed coiled proximal end in a deployed position, each of the ends being in the non-deployed positions while being inserted into a first and a non-connected second body lumens, and each end having configurations which self-radially expand to the deployed position in the first and non-connected second body lumens urging and positioning the first and non-connected second body lumens together along the longitudinal axis and become connected; and

an elongated body introducer for introducing the proximal and distal ends into the first and non-connected second body lumens in their non-deployed

positions, and wherein upon removal of the elongated body introducer from the body lumens the proximal and distal ends self-expand to their deployed positions.

38. An anastomosis device for a bladder with an associated urethra, comprising:

a generally elongated body with a longitudinal axis, a proximal end, a distal end and a connecting member connecting the distal and proximal ends, with a non-deployed distal end and a non-deployed proximal end in a non-deployed position, each end having configurations which self-radially expand to a deployed distal end and a deployed proximal end in a deployed position, each of the ends being in the non-deployed positions while being inserted into the urethra, and the distal end being inserted into the bladder in the non-deployed position, and each end radially expanding to the deployed position in the bladder and the urethra urging and positioning the bladder and the urethra together along the longitudinal axis and become connected; and

an elongated body introducer for introducing the proximal and distal ends into the first and non-connected second body lumens in their non-deployed positions, and wherein upon removal of the elongated body introducer from the body lumens the proximal and distal ends self-expand to their deployed positions.

39. An anastomosis device, comprising:

a catheter having a catheter distal end to be placed in a patient's body and a catheter proximal end, the catheter having a tube with a main lumen extending from substantially the catheter proximal end to substantially the catheter distal end of the, the tube including a first cut-out portion and a first distensible member positioned adjacent to the first cut-out portion, the catheter including an actuating device to distend and un-distend the distensible member; and

a passive fixation device positioned around the tube of the catheter comprising, a generally elongated body with a longitudinal axis, a proximal end, a distal end and a connecting member connecting the distal and proximal ends,

with a non-deployed distal end and a non-deployed proximal end in a non-deployed position, the proximal and distal ends being expanded by the first distensible member to a deployed proximal end and a deployed distal end, each of the ends being in the non-deployed positions while being inserted into a first and a non-connected second body lumens, and each end becoming radially expanded in the deployed position in the first and non-connected second body lumens urging and positioning the first and non-connected second body lumens together along the longitudinal axis and become connected.

40. A method for the anastomosis of a bladder to a urethra, comprising:

providing an anastomosis device including, a catheter with a tube including a main lumen and at least one inflatable balloon, the catheter including a distal end and a proximal end, and a passive fixation device positioned at the exterior of the catheter around the tube, the passive fixation device including a passive fixation device distal end and a passive fixation device proximal end with each being expandable to deployed positions and each end of the passive fixation device being non-expanded in non-deployed positions;

introducing the anastomosis device into the urethra with the proximal and distal ends of the passive fixation device being in non-deployed positions;

deploying the passive fixation device proximal end in the urethra to the deployed position so the passive fixation device proximal end becomes retained in the urethra; and

deploying the passive fixation device distal end in the bladder to a deployed position so the passive fixation device distal end becomes retained in the bladder.

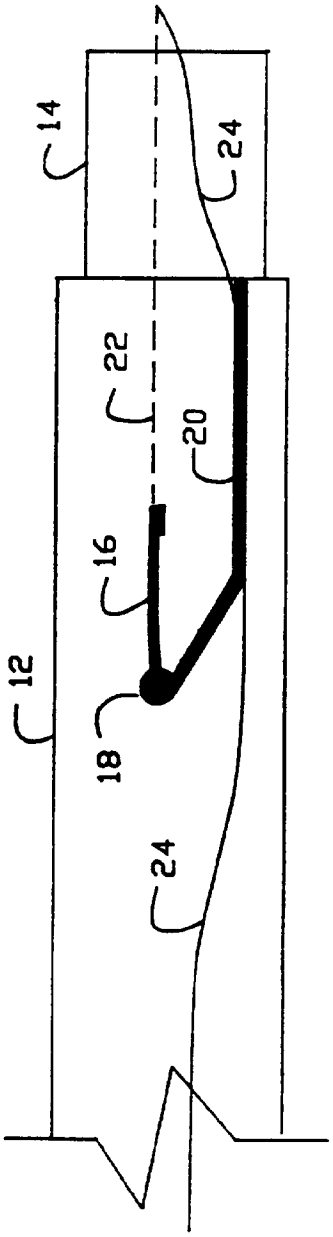

FIG. 1

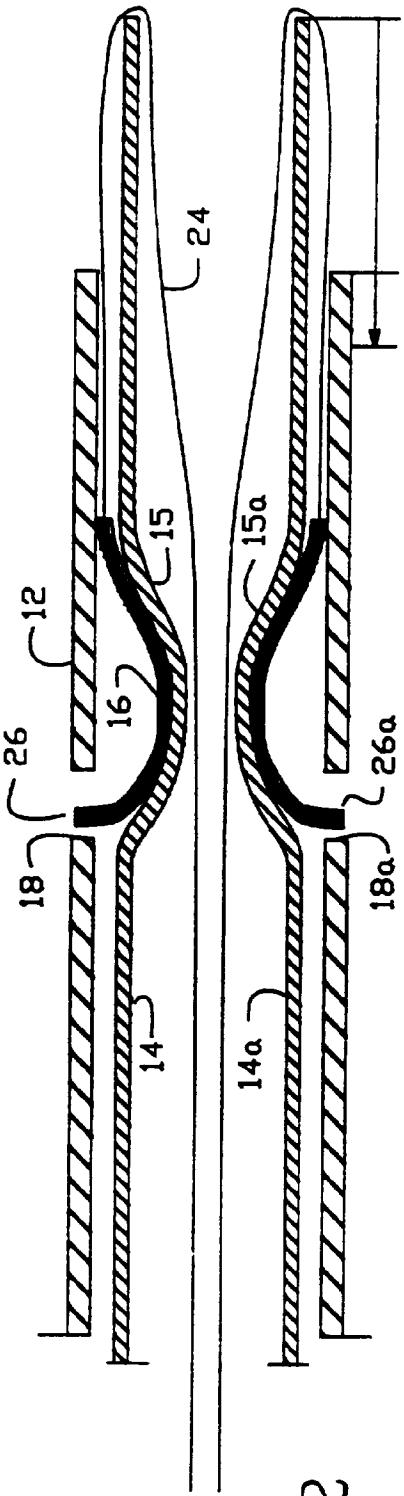

FIG. 2

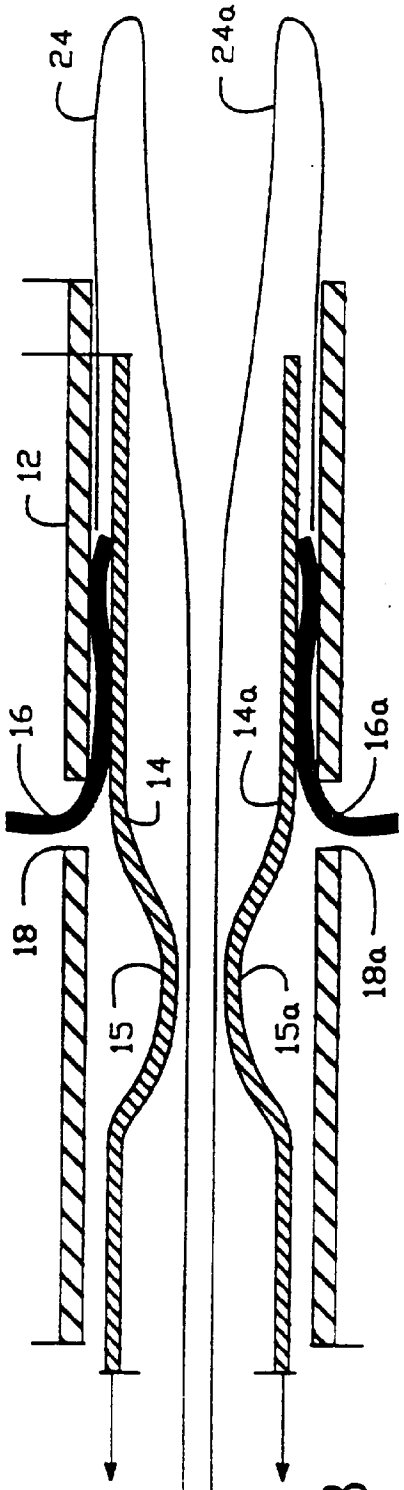

FIG. 3

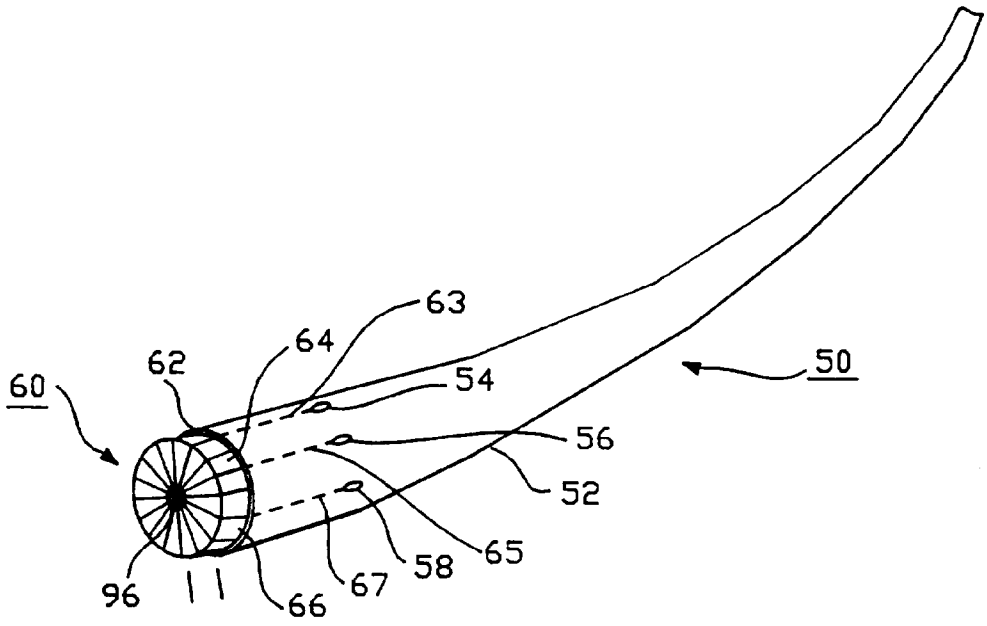
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FIG.4

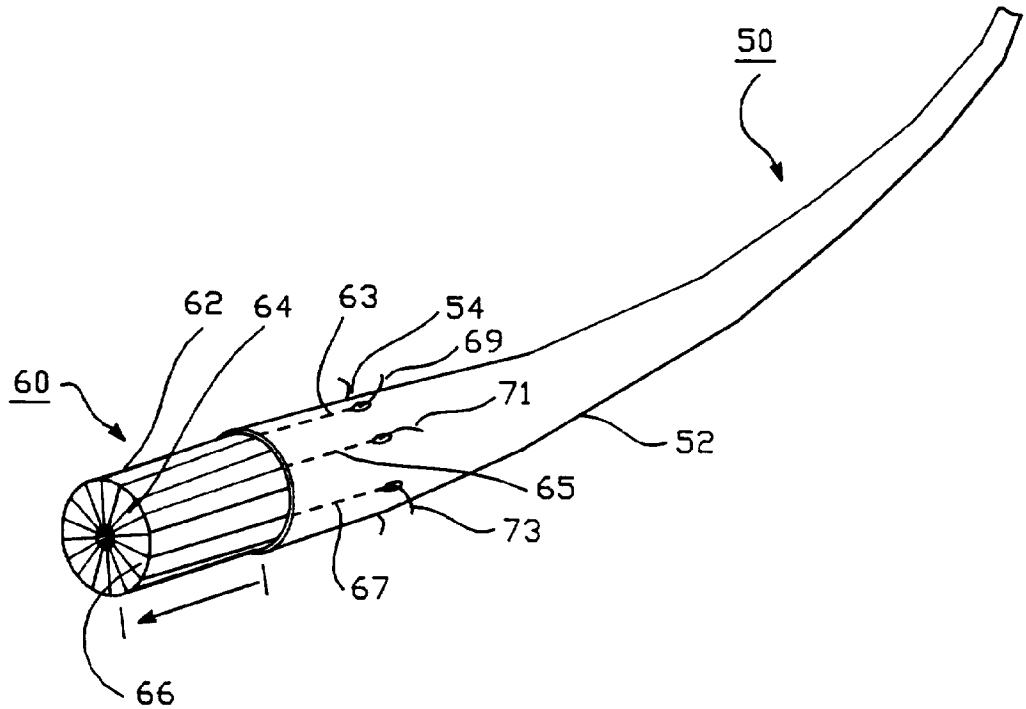
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FIG.5

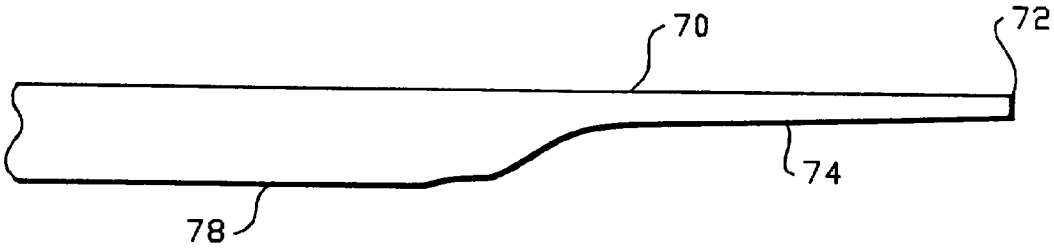

FIG.6

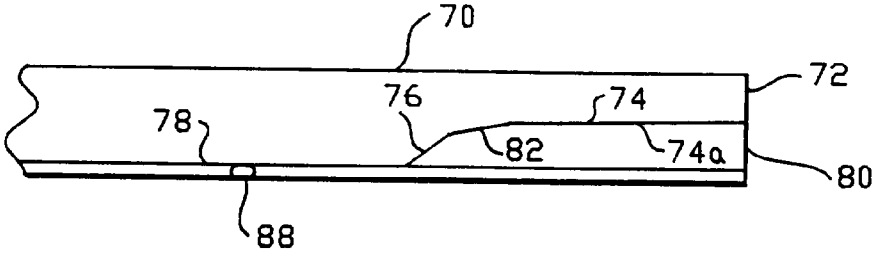

FIG.7A

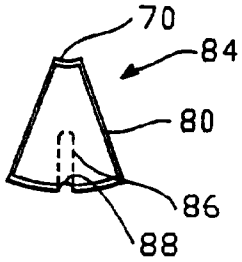

FIG.7B

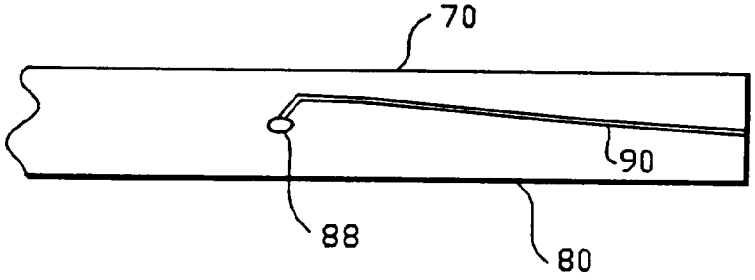

FIG.8A

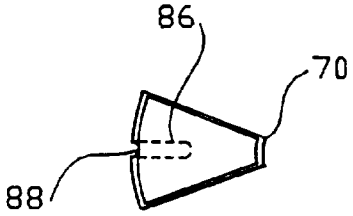

FIG.8B

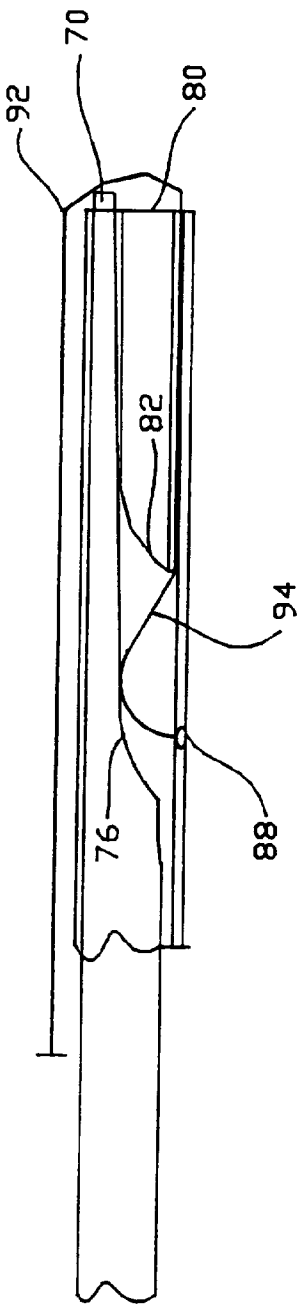

FIG. 9

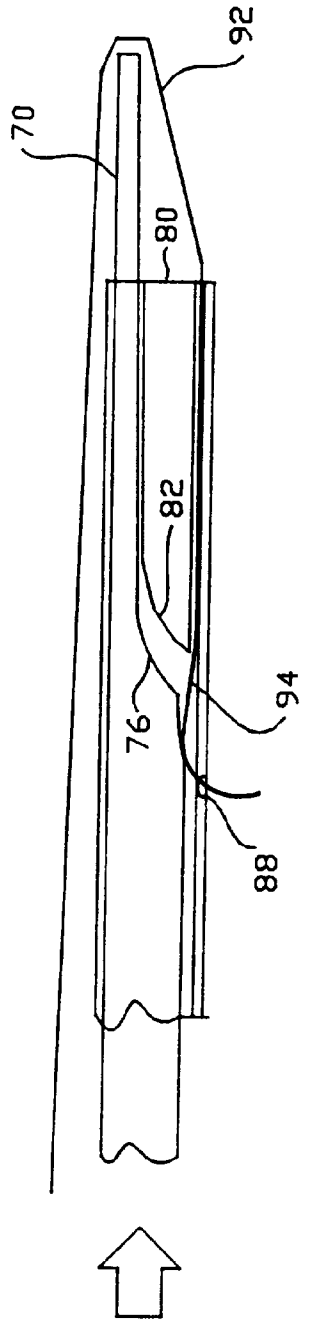

FIG. 10

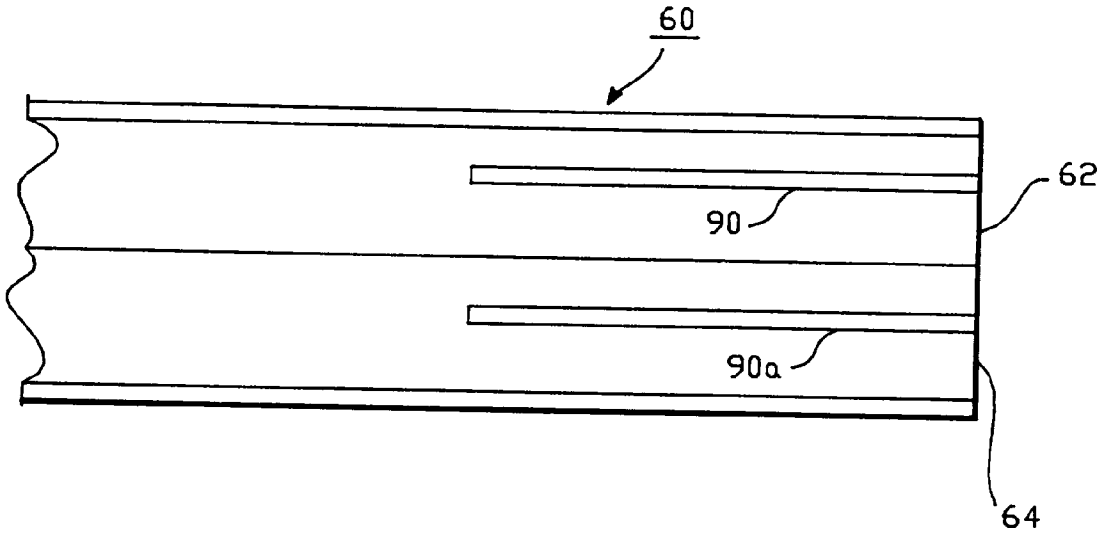

FIG. 11A

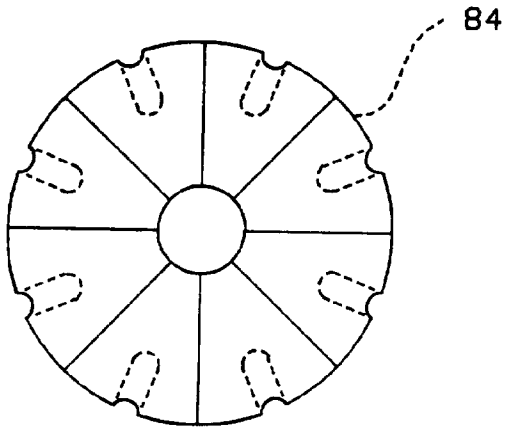

FIG. 11B

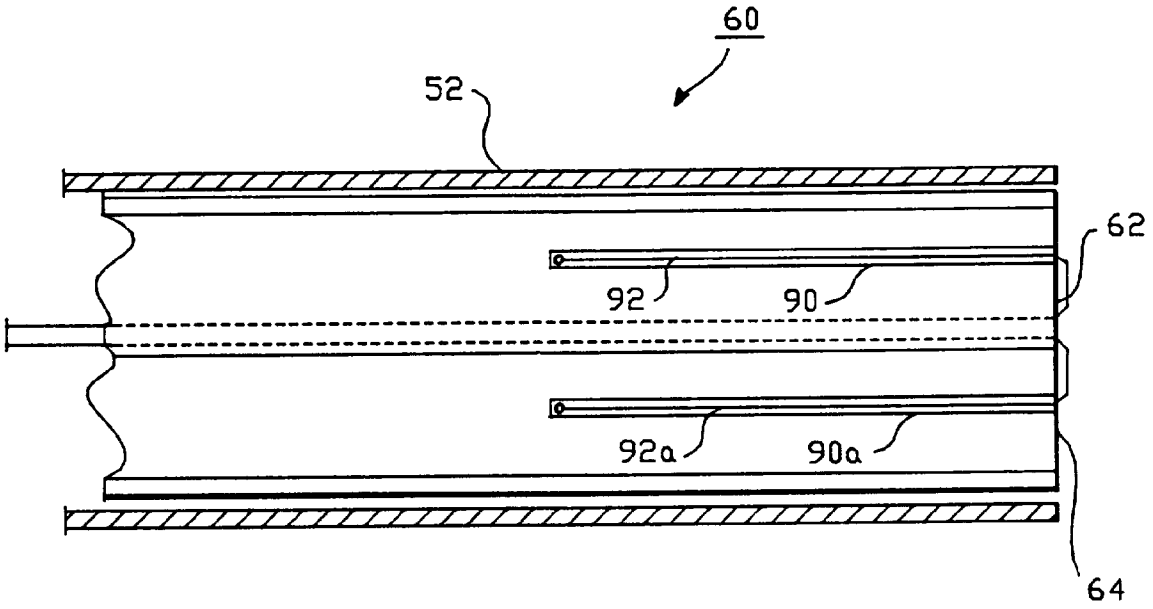

FIG. 12A

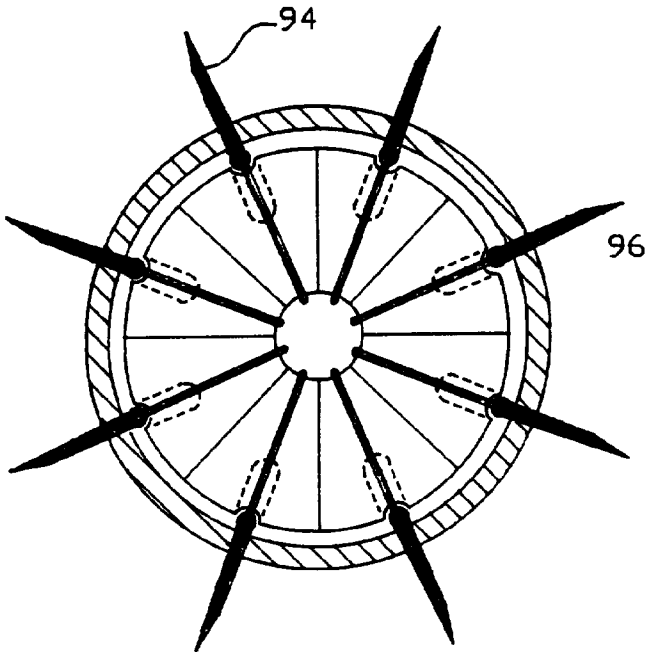

FIG. 12C

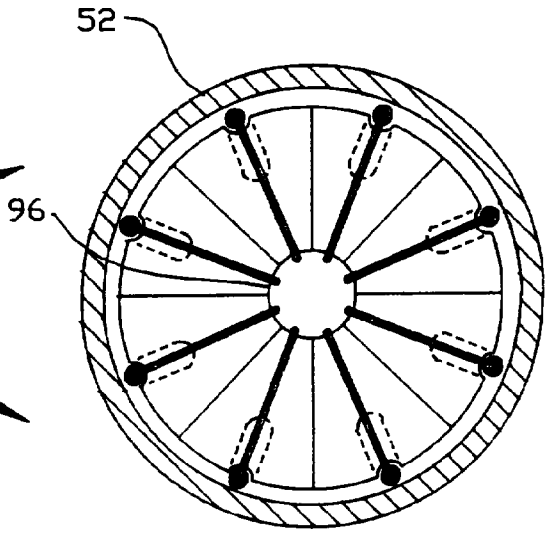

FIG. 12B

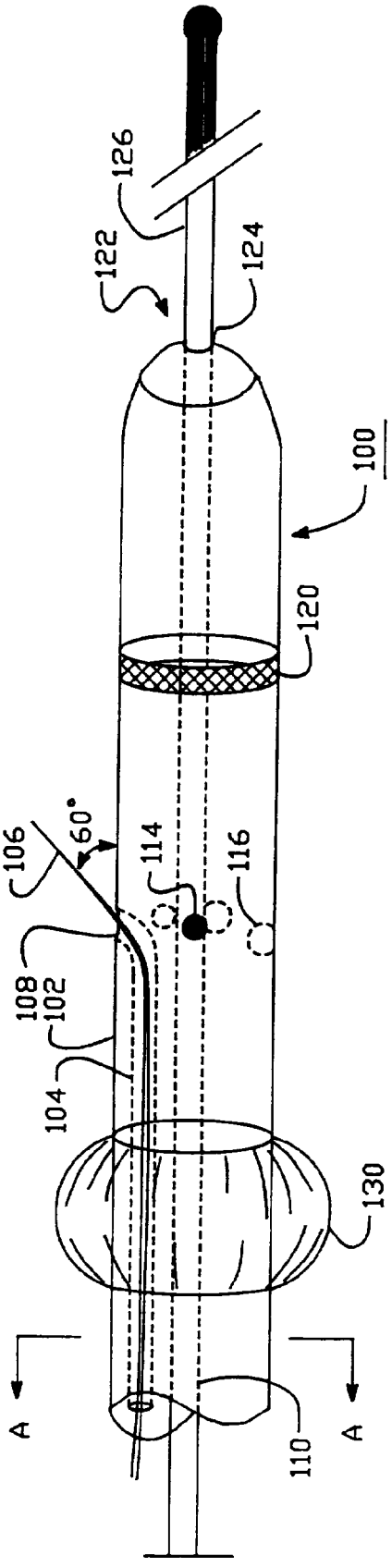
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FIG. 13

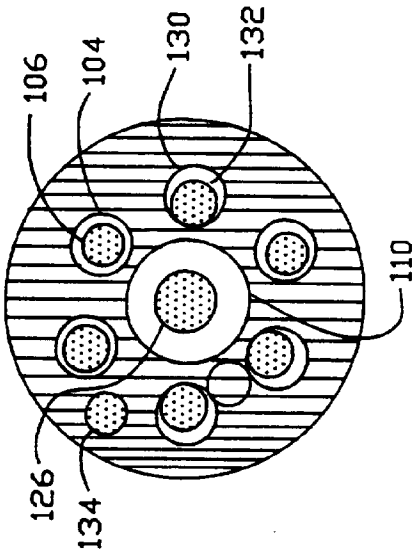
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FIG. 14

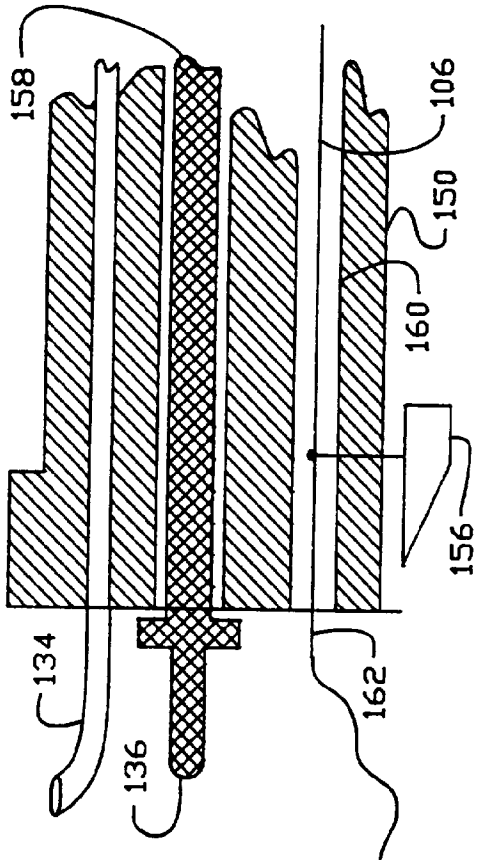

FIG. 16

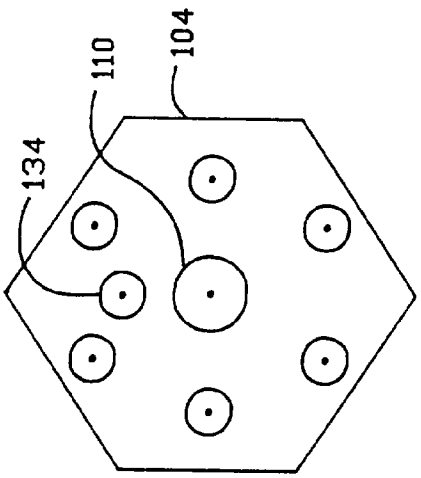

FIG. 17

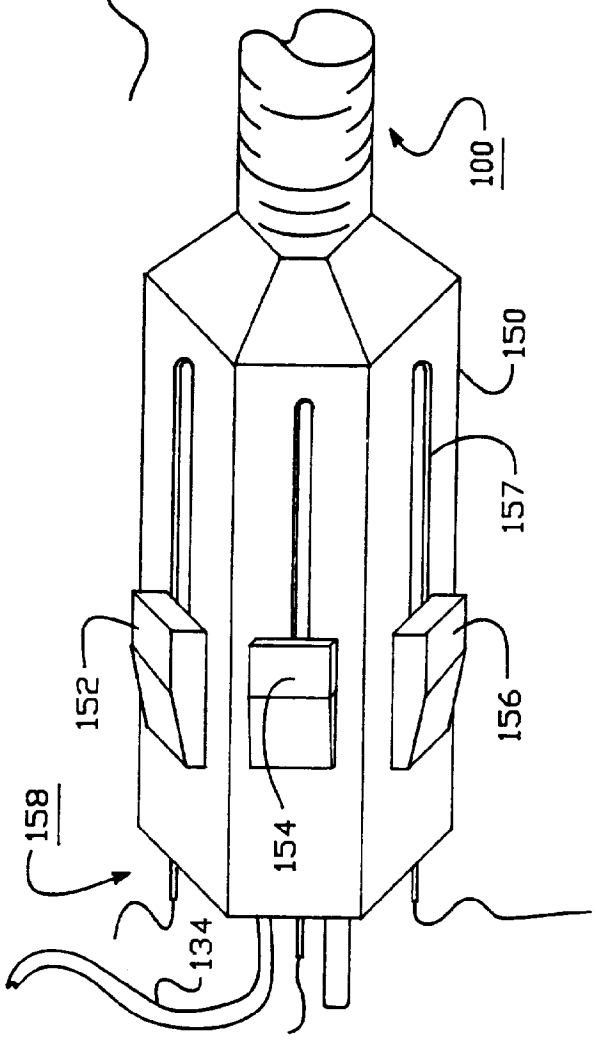

FIG. 15

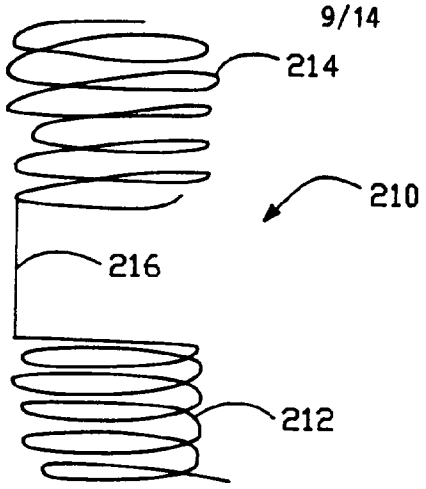

FIG.18

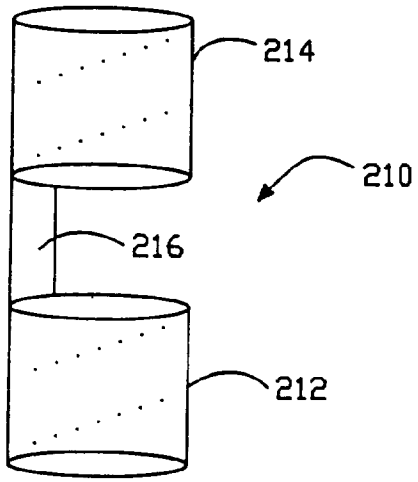

FIG.19

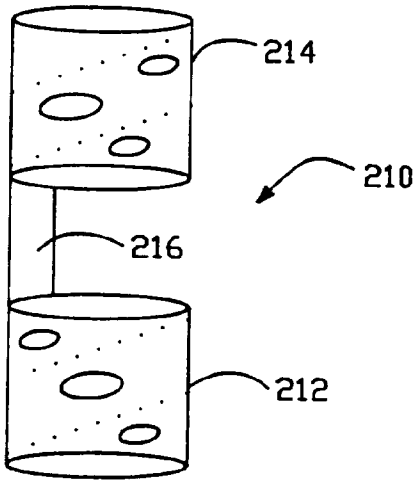

FIG.20

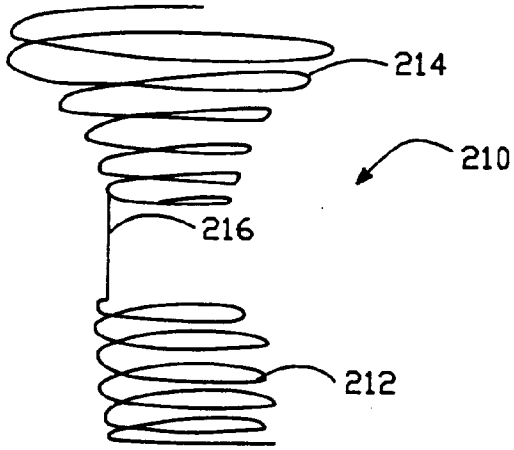

FIG.21

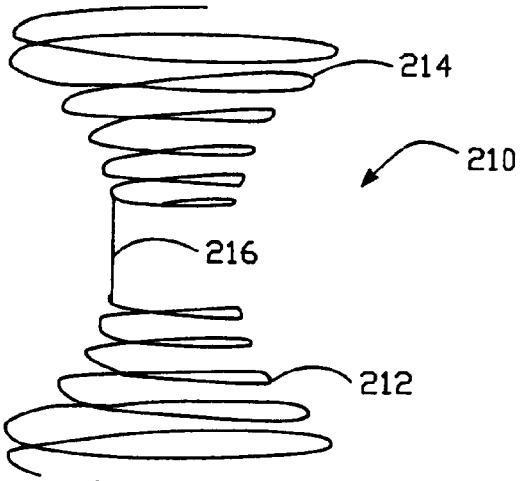

FIG.22

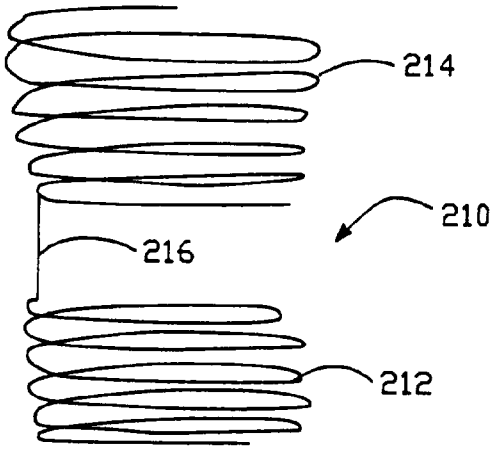

FIG.23

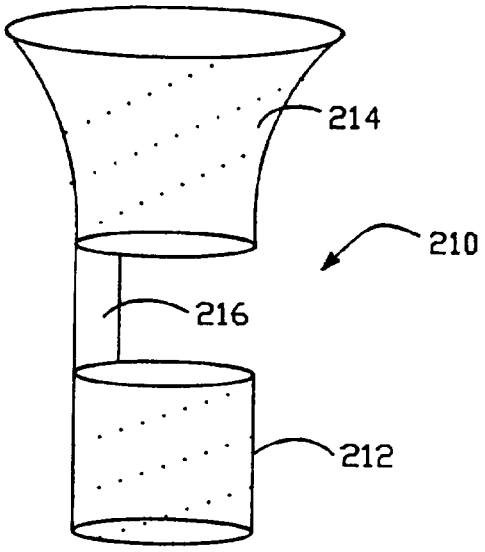

FIG.24

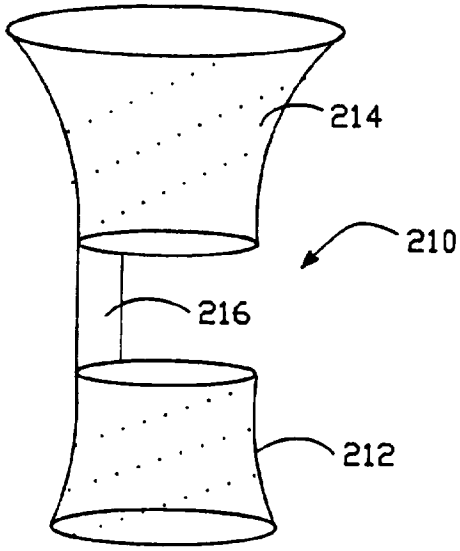

FIG.25

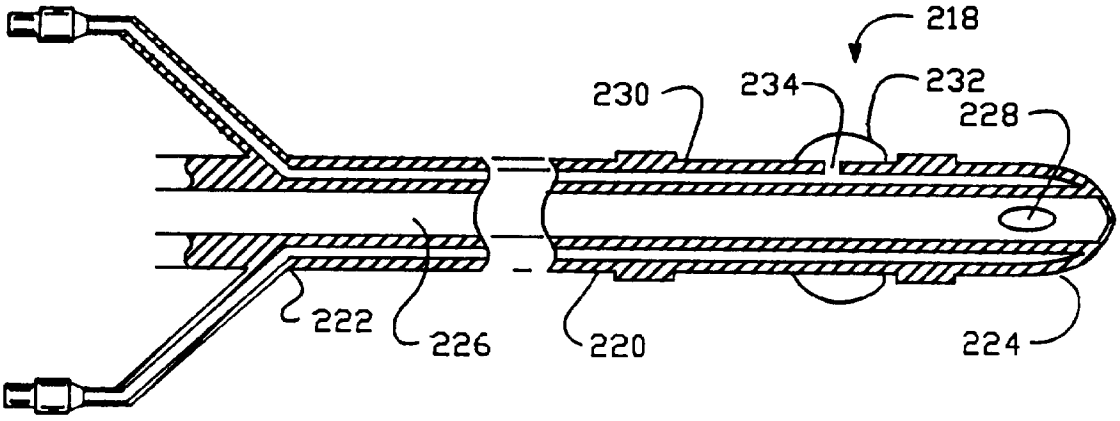

FIG.26

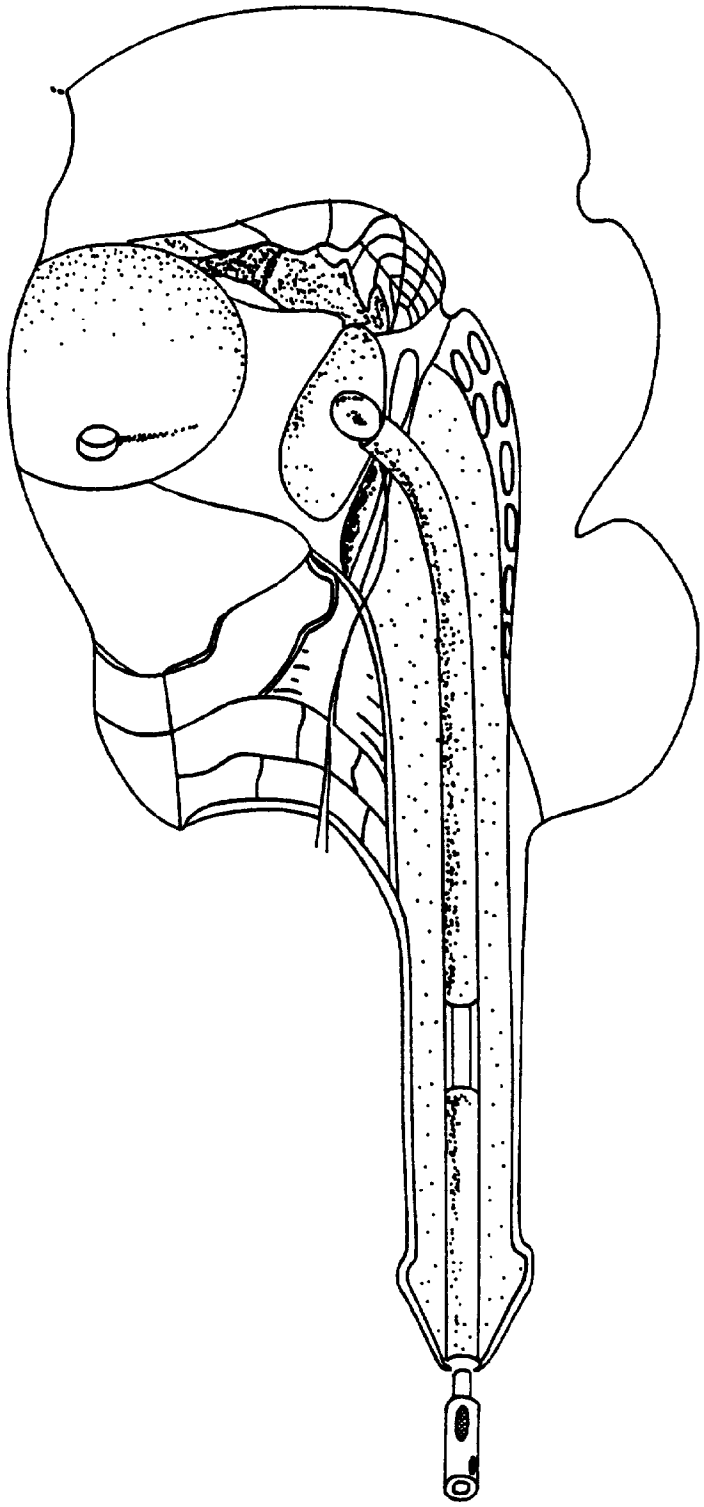

FIG.27

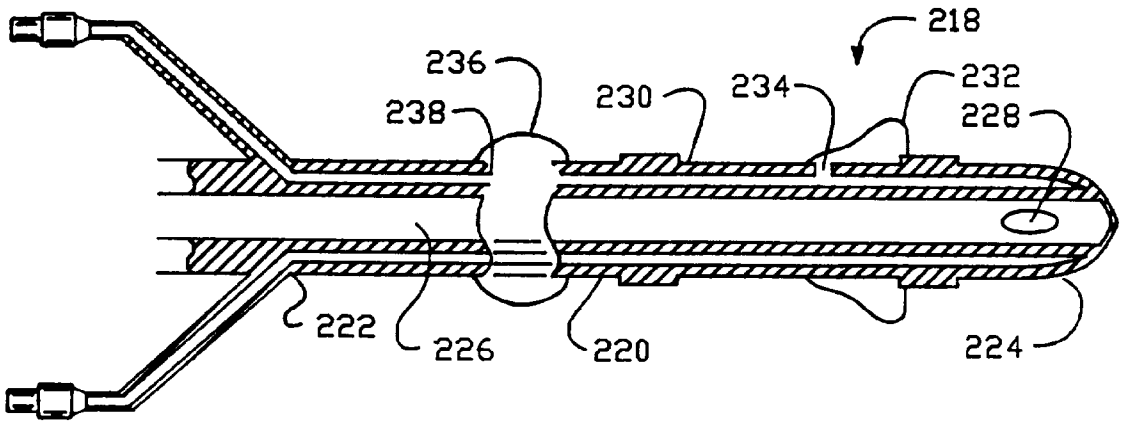

FIG.28

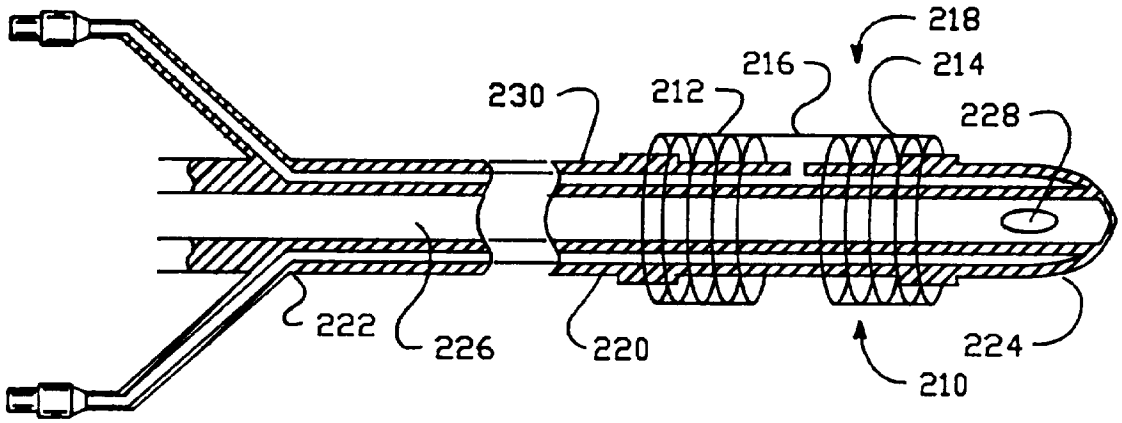

FIG.29

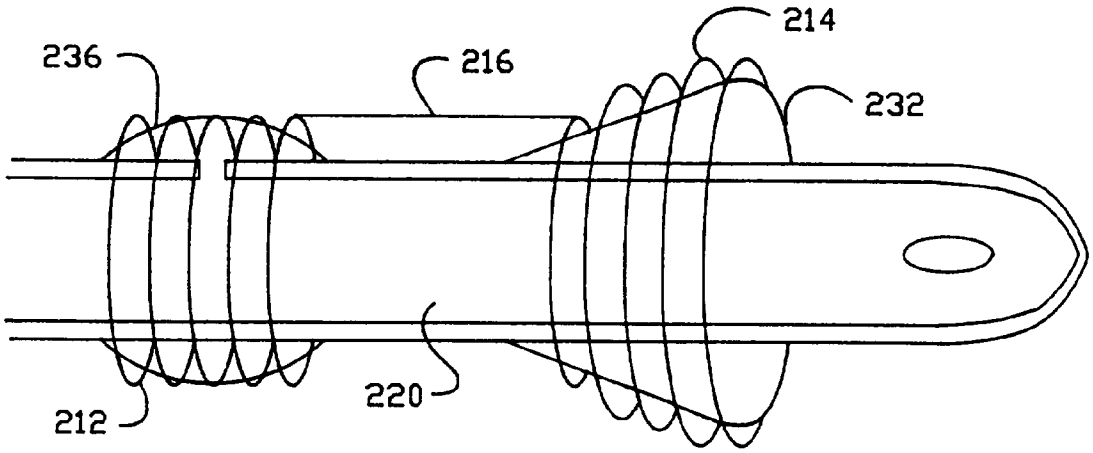

FIG.30

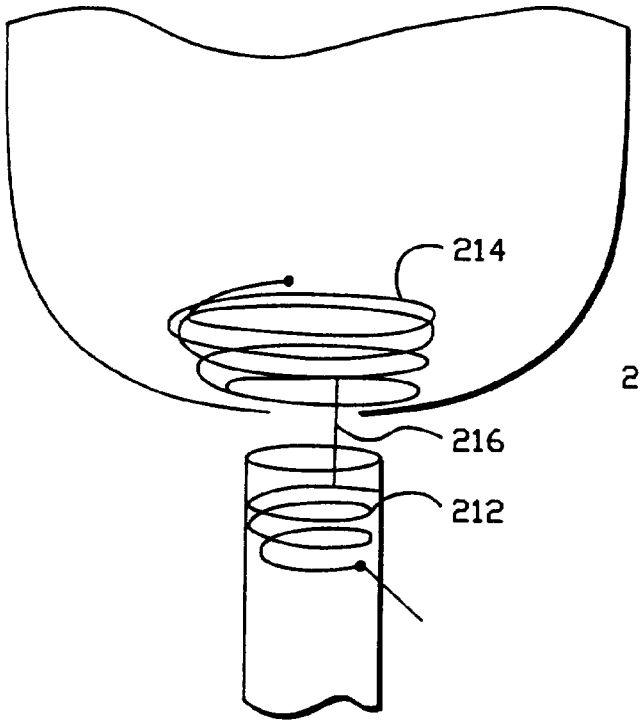

FIG.31

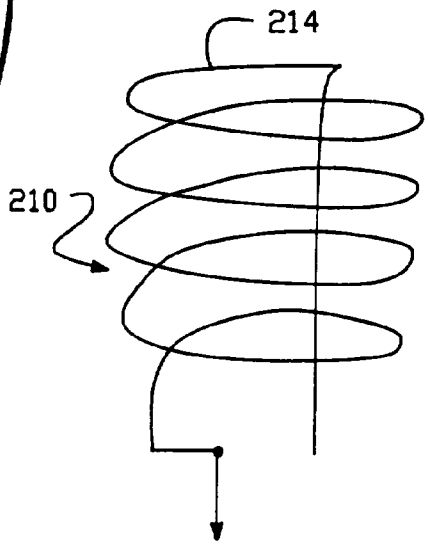

FIG.32

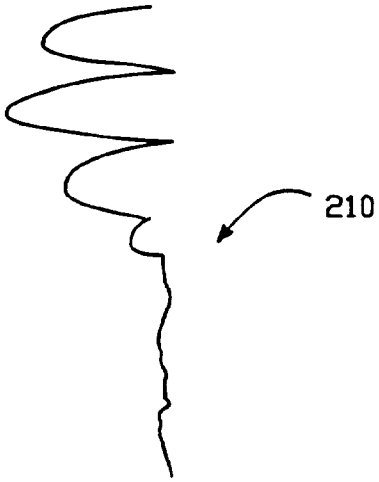

FIG.33

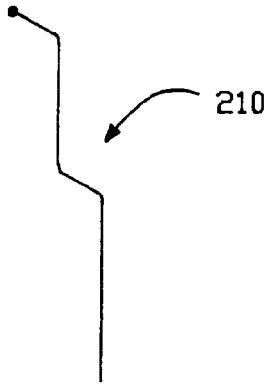

FIG.34

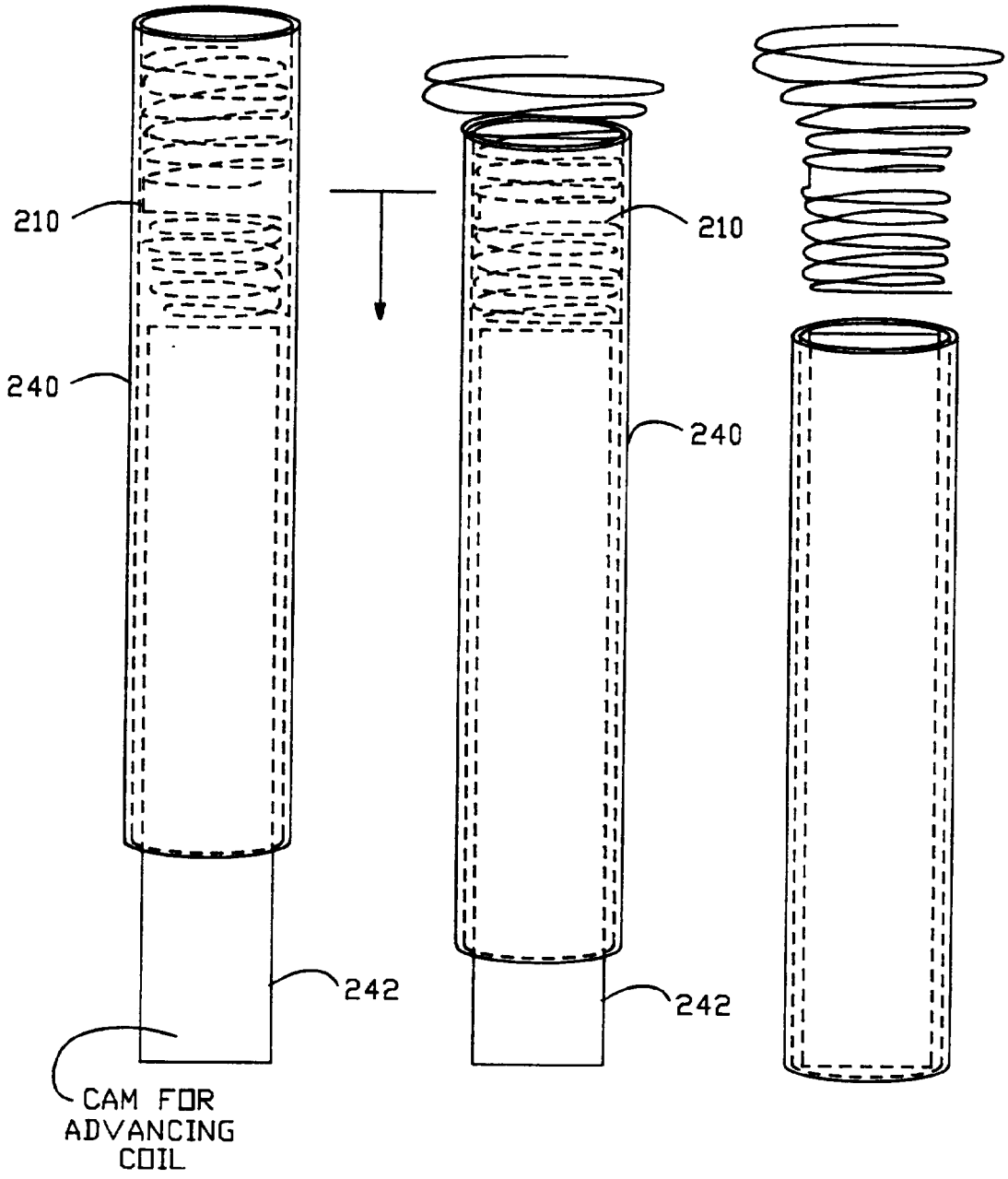

FIG.35 FIG.36 FIG.37

INTERNATIONAL SEARCH REPORT

Interr nal Application No
PCT/US 95/12247

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/11 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO,A,94 05213 (LAURUS) 17 March 1994 see figure 18	1 11,25
X	EP,A,0 589 409 (USSC) 30 March 1994 see column 6, paragraph 3; figure 1	1
X	EP,A,0 542 126 (HEIDMÜLLER) 19 May 1993 see abstract; figure 2	1
A	US,A,4 553 543 (AMARASINGHE) 19 November 1985 cited in the application see abstract; figures 3,4	1,11,25, 29
A	EP,A,0 480 428 (WILSON-COOK) 15 April 1992 see figure 2	29
A	DE,C,320 438 (HAUMAN) 19 September 1919	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

2

Date of the actual completion of the international search	Date of mailing of the international search report
23 January 1996	19.04.96
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Authorized officer BARTON, S

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Ir ·national application No.
PCT/US95/12247

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 40
because they relate to subject matter not required to be searched by this Authority, namely:
See Rule 39.1 (iv) PCT

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1: Independent claims 1,11,25 and 29 together with dependent claims 2-10, 12-24, 26-28 and 30-35.

2: Independent claims 36-39.

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-35

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/US 95/12247

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9405213	17-03-94	US-A-	5458609	17-10-95
		US-A-	5364408	15-11-94
		AU-B-	5017893	29-03-94
		JP-T-	8501005	06-02-96
		CA-A-	2142965	17-03-94
EP-A-0589409	30-03-94	CA-A-	2106127	24-03-94
		US-A-	5403329	04-04-95
EP-A-0542126	19-05-93	DE-C-	4137218	11-02-93
		US-A-	5320632	14-06-94
US-A-4553543	19-11-85	EP-A-	0173736	12-03-86
		WO-A-	8503858	12-09-85
EP-A-0480428	15-04-92	US-A-	5088979	18-02-92
		AU-B-	4617893	18-11-93
		AU-B-	643076	04-11-93
		AU-B-	8569791	11-06-92
		CA-A-	2053130	12-04-92
		JP-A-	4226644	17-08-92
		JP-B-	6038802	25-05-94
		US-A-	5226876	13-07-93
DE-C-320438		NONE		